AMERICA'S BLOOD CENTERS

BLOOD ESTABLISHMENT COMPUTER SOFTWARE (BECS) CONFERENCE

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LIST OF PARTICIPANTS:

JIM MacPHERSON
CEO, America's Blood Centers

DON DODDRIDGE
President & CEO, Florida Blood Services

SHERYL KOCHMAN
Chief, Devices Review Branch, OBRR/CBER/FDA

RODEINA DAVIS
VP CIO, Information Services, Blood Center
of Wisconsin

MARSHA SENTER
Products Manager

LINDA WEIR
Expert CSO, FDA/CBER

T.W. WALKER
Executive Director of Regulatory affairs
And Quality Audits, Canadian Blood Services

ANGUS MACMILLAN DOUGLAS
Consultant, Alliance of Blood Operators

JOAN LORENG
National Expert investigator, Biologics, FDA/CBER

TAMARA POLING
Information Systems Committee, AABB

JEFFREY McCULLOUGH
MD

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P R O C E E D I N G S

(8:30 a.m.)

MR. MacPHERSON: Good morning. When we budgeted for this conference, we figured 50 to 60 attenders. We have 170 registrants. So it's going to be very cozy for the next 2 days. And hope you appreciate that, and it will get -- it will force the network be even more so. We have people from all over the world here at this conference. It's interesting conference, the first of its kind to address these kinds of issues. And I'm going to give a bit of an introduction.

I'm Jim MacPherson. I'm the chief executive officer of America's Blood Centers. And I'm just going to give you a little bit of background. I'm going to go through it very quickly because a lot of you understand this and know this. Just to tell you who are the sponsors and who's been involved in this. ABC took the lead on this in cooperation with the Alliance of Blood Operators.

Now, the Alliance of Blood Operators is a -- if you will, a burgeoning trade association, if you will, of trade associations that includes at this point, ABC, the American Red Cross, the Australian Red Cross blood

transfusion services, Canadian Blood Services, the European Blood Alliance, and the NHSBT, which is the English Blood and Transplant Service.

We are looking to figure out how we can open up membership in the future without sort of becoming deluged, but that's who we are right now. We've been around for about 3 years.

CBER, part of FDA, the Center for Biologics Evaluation and Research, is a cosponsor, and was very heavily involved in all the planning, very supportive, and I want to thank certainly Alan Williams and Jay Epstein and all the people from CBER who have been very cooperative and helpful through getting this thing together and helping to get it organized.

Additional sponsors -- AABB, AdvaMed, and the American Red Cross. And as I said, American Red Cross is a member of ABO. This is the planning committee. Wasn't quite a cast of thousands, but it was an interesting group to get together, and especially want to recognize Rodeina Davis as co-chair, along with Becky C (phonetic) from blood services, the quality source.

And you can see this. It's a good group of

people and very representative. There are four CBER people on the planning committee. Let me just go through a little bit of history for backgrounds to frame this, and then I'll introduce Don Doddridge who is ABC's president, to talk a little bit about what we are going to do today and where we are going to go.

And this is from memory, so I -- if the facts are slightly off, forgive me, I'm sure someone will correct me. But in the early 1990s, after a major recall and several major incidents involving unvalidated blood center manufacturing software, ABC -- at that point it was CCBC -- we sent a letter to CBER requesting that CBER regulate software as a medical device.

So if you want to look at the enemy here, it's us. We asked for this, and so here we are 15 years later, saying we didn't mean it. No, we -- saying, well, we've got a problem -- (tape interruption) -- oh, excuse me --

(Laughter)

MR. MacPHERSON: Now, the rationale at that point was there was little or no blood center expertise and computer software to really understand what was in the black box. That frankly was it, and that's -- that was the

overwhelming opinion from our members. Well, certainly times have changed.

In 1994, FDA issued a letter stating that it would treat software intended or used in the manufacture of blood and blood components as a medical device that needs to be separately cleared by FDA through the 510(k) process as you are all aware. But then we got the suspenders. In the late 1990s, FDA said that just like every other manufacturing facility that's regulated by FDA, that we needed to extensively validate the software before it's used.

Now, that approach of validation before use has been adopted worldwide. Some of you, I'm sure, are aware of PICs (phonetic) -- I forget what it stands for. Someone -- I'm sure someone can tell us. But anyway, there is a -- the PIC standards. It's sort of a self regulation, but it's a group of manufacturers along with the regulators of various different countries.

They work together to come up with standards -- voluntary standards that organizations will implement. And they -- and actually I found out -- I didn't realize that there is a PIC standard or a PIC guide that pertains to

blow establishment software that was released late last year. And the number is, as you can see, is on the slide.

More recently, FDA had stated that software used in the clinical setting, the cross-matching, transfusion services, tracking blood to patient bedside would be subject to 510(k) clearance if controlled by a licensed blood establishment, which I think is also sort of stimulated saying okay, do we really want to go there, and if so, how do we want to go there?

Now this is, of course, the biased opening point of view, but the unintended consequences of the way BECS are regulated at this point. And again, this is my opinion so you can throw brickbats at me. Worldwide blood establishments are served by a -- have -- wind up being served by a niche industry of poorly capitalized software houses.

Now, this is not a bad thing to say about any of the software houses that are represented here, and you are here in very large numbers. But the reality is that it is a niche industry of mostly small and a few medium-sized software houses. Available software is usually years behind what's technologically available off the shelf, and

changes are slow and expensive, because again, these are fairly small companies and they are struggling to keep up.

State-of-the-art and reliable off-the-shelf and Web-based software available to pharmaceutical manufacturers is not available in the U.S. Now, I make a point of this, because we are the only industry, the blood establishments are the only industry that are subject to 510(k) requirements. The pharmaceutical industry is only subject to validation requirements.

So the result is manufacturers such as Microsoft, Adobe, SAP, which are heavily involved in the pharmaceutical industry, refused to serve the blood establishments because of the 510(k) requirements. Now yesterday, our IT consultants from a company called Lunexa in San Francisco made a presentation, and I inserted this slide. So this is not in your folder, but we can get copies to you if you want.

But it doesn't really say too much, except what I was struck by is that he gave an analysis of the industry compared to other industries. And what he said -- and he is in the room and so if I misquoted him or over-quoted him, I'm sure he'll correct us. But basically, unlike any

other manufacturing setting, the blood center niche market created by 510(k) regulation, there is no what's called "ERP," and I just found out what that is yesterday.

And I remember -- I think its enterprise research, but I don't know what the "P" stands for, meaning -- but meaning end-to-end manufacturing software in the blood center market -- there is none. What we are doing is putting pieces together, the regulated software versus all the other pieces that we need to run our business to control personnel, to control training records.

All this that's not regulated, we have to put these pieces together. And so, those systems don't naturally talk to each other, and that requires us to put fixes together for that, because we are just putting pieces together, which is another risk involved in doing this. And the systems don't talk to each other.

In ERP manufacturing software, the systems are designed so that they do talk to each other. But our systems don't talk to each other. And therefore this lack of coordination means no easy means of correlating -- correlation of practices or experiences. And this is -- as I said in the beginning, this is sort of unprecedented in

manufacturing setting, so.

Now, this leads to two questions and again, this is -- these are my biased views of things, but we've -- this has pretty much come from a lot of discussion within -- certainly within our organization and with the American Red Cross and with other organizations. Does BECS still uniquely require both 510(k) clearance and user validation requirements? Are the benefits of 510(k) clearance which are poorly documented, worth the risk of unintended consequences?

And are there alternative ways to both assure the confidence of the regulators and the needs of the blood establishments? So starting giving that overview, let me introduce Don Doddridge, as I said, who is the president of America's Blood Centers and the president of Florida Blood Services in Tampa St. Pete, to tell us what we are going to be doing today. Thanks, Don.

MR. DODDRIDGE: Thank you, Jim. Just a couple of housekeeping. We -- I know as we all have cell phones, I don't think anybody travels without one, if you do have a cell phone, make sure it's either turned off or on vibrate. And another housekeeping; the restrooms are at the back of

the room in the hallway. And we will have a morning break, then break for lunch, and then we'll have an afternoon break.

I'd like to welcome you to this conference. There's many people out here that are good friends, and we've been friends for many years. I guess we're all getting a little greyer over the years. And this is our first attempt at a Blood Establishment Computer Software Conference, as Jim spoke about.

Before I introduce the first presenter, I'd like to briefly describe the goals and the structure of this conference and -- so that we can proceed. BECS conference is a workshop for information technology stakeholders in the blood banking community. The aim of the workshop is to answer two multifaceted questions.

Do the current regulations of BECS not only help ensure the safety of the blood supply, but also allow blood centers to keep abreast of the most current advancements in blood banking and in software? And if not, why not, and what step should we -- be considered to modify that current situation? Now, if we accomplish that today that will be a miracle, but if we make some first step so that I think

everybody will say that this conference was a success.

We've had a committee of representatives from blood centers, national blood organizations, the federal government who had planned, I think, an excellent program today. During the first part you will get a better overview of the IT landscape including facts about the software blood centers use, how it's validated, and why it is regulated to the 510(k) process.

During the second half, participants will take that information, and in breakout sessions during this afternoon, we will have a panel discussion. And tomorrow we'll attempt and hopefully reach some common ground on ways that the current scheme works, and ways that it can be improved. And hopefully, while we're on that common ground, we'll all agree on the next steps.

So keep that in mind as we go through this process. Hopefully by tomorrow afternoon, there will be some agreement among all the parties involved. It's a special pleasure today to have with us Dr. Jeff McCullough. And Jeff, where are you in the room here? Jeff, please stand up. Jeff is a longtime friend, and I'll call him a pioneer in transfusion medicine.

He's been a strong supporter of the blood banking community and been, like I said, with his work in -- with transfusion has been outstanding, and we're lucky to have him with us today. Jeff will be helping us frame our questions today; he will be playing the devil's advocate, and hopefully challenging us to find more innovative solutions when we get stuck.

Towards the middle and the end of each day, he will review and crystallize the issues and recall highlights from the presentations or comments that help us reach some consensus on what is needed to move forward. After lunch there will be breakout slips available at the registration desk in the foyer.

Each breakout will have a slightly different topic, and you are encouraged to pick up a slip for the breakout session which you have an interest in. If the slips are gone for a particular breakout session, please take the next slip of your second choice. You will find the breakout topics on your agenda in your packets, and there will be breakout facilitators and scribes at each sessions.

Before I introduce our first speaker, I'd again

like to thank the AABB staff who have done an excellent job in putting on this conference. And Bob, special thanks to you for helping to keep us all together here. And now, I'd like to introduce our first speaker.

Our first -- since FDA regulation is one of the central issues of this conference, appropriately our first speaker is from the FDA. Sheryl Kochman oversees all aspects of the BECS device review program in OBRR, and she is well qualified to give us a short lesson on the history and rationale of regulated BECS as a medical device. So with that, I'd like to welcome Sheryl. Please, Sheryl.

(Applause)

MS. KOCHMAN: Thank you. As I'm sure you can imagine, AABB and ABC were instrumental in bringing this to fruition. FDA is grateful to be here and to bring the issues to the surface, to have a chance to speak in an open forum. And it's been a long process, but hopefully it's going to one that's worth the products of the two days.

With that -- most of my talk is probably going to be ancient history to many of you. I won't call them "fond memories," but they are probably memories.

(Laughter)

MS. KOCHMAN: I have a lot of slides, but many of them, as I said, are a rehash of ancient news, so I'll go through them quickly. My objectives are to help you understand the issues that led to the review of BECS as medical devices, to understand FDA's current perspectives regarding regulation of software in general, to understand the regulation of medical devices, and to understand the assignment of responsibility for software as equipment versus software as a medical device.

As you all recall, initially when blood banks started using software, FDA was regulating it as if it were an instrument or a piece of equipment in the laboratory. We were not at that point regulating that other device at the manufacturing end of things.

In the late 1980s, FDA started noticing that because of HIV the number of donor-screening questions asked significantly increased, as did the number of tests performed that's resulted in increases in the volume of data to manage. Reliance on computerized data management and automation became very prevalent as opposed to the careful personal checks and double-checks that were being done annually.

And as you can imagine, errors leading to the release of unsuitable units of blood were bound to happen. In 1988, in response to congressional concern about the safety of the blood supply, FDA initiated 100 percent inspection of blood establishments. And I want to quickly go over the timeline from that point to where we are today.

In April of 1988, the FDA issued two different memos to blood establishments, one about the control of unsuitable blood and blood components, and another about the recommendations for how to implement computerization in blood establishments. That was followed a little over a year later with a memo to blood establishments specifying requirements for computerization of blood establishments. That was September 8, 1989.

Interestingly, November 13, 1989, the draft FDA policy for the regulation of computer products was made available. This described FDA's authority to regulate computer hardware and software products. It described three levels of regulation based on risk to the patient if the software were to fail.

It described current and future exemptions. It described the 510(k) process and the PMA process. As I

said, it's interesting that this came out shortly after the inspections were started. It specified that computer hardware and software used in blood banks would not be exempt from the regulation.

Then in March -- on March 20th of 1991, two memos, two additional memos were sent to blood establishments; one, the responsibilities of blood establishments related to errors and accidents in the manufacture of blood and blood components, and another, deficiencies relating to the manufacture of blood and blood components.

We are continuing to hope that we could regulate and help people understand how to validate. So in September of 1993, the draft guideline for the validation of blood establishment computer systems was made available. The target audience for this document is the manufacturer of blood and blood components, not software manufacturers.

Then in November of 1993, there was an FR notice stating that there would be a workshop on validation of BECS. And it made known the availability of the draft guidance and it requested comments. The workshop occurred on December 6th and 7th 1993, which was called workshop on

validation effects.

On March 31, 1994, a memo to Blood Establishment Computer Software manufacturers first went out. It stated that software used in blood establishments is a medical device. And shortly afterwards, there was a talk paper published April 13th of 1994. It stated simply at the top "Blood Establishment Computer Software regulated."

What's important to note here is that it clarified the term "blood establishments" includes blood banks, blood centers, blood product testing laboratories, plasma freezer centers, and transfusion services. So it was made clear as far back as 1994, of all the places that FDA acknowledged, this type of software was being utilized.

Then in August of 1994, the March '94 letter was actually published in the Federal Register rather than simply being mailed out and posted on a Website or something. February 10, '95 a letter to BECS manufacturers announced that the deadline for submission of 510(k)s was March of 1996. This gave people just over a year to get their things together and submit it.

On July 11th of 1995, there was another workshop addressing quality. This one -- I'm sorry, another

guideline addressing quality -- this one, "Guideline for Quality Assurance in Blood Establishments." I put this here because this one also included references to validation of computers and that sort of thing.

In October 3rd of 1995, there was an FR notice that published the February 10, '95 letter, and also an extension of the time period for the pre-market submissions. November of '95 there was also a memo to blood establishments, guidance to -- for blood establishments concerning conversions to FDA-reviewed software products.

We stated at that time that we believed software conversion should be completed by March 1996, but that we would handle request for extension on a case-by-case basis. May 7th of '96, we felt a need to a send a letter to BECS manufactures reminding them of our previous letter, telling them to submit a 510(k).

And on January 13th of 1997, the guidance, "Reviewer Guidance for a Pre-Market Notification Submission for Blood Establishment Computer Software" was published. This was the document that was developed, because this was a brand new program. This was the first time we were

going to be looking at software.

We knew we would be looking at a lot of submissions at the same time. We knew it would be critical to ensure consistency in the review process. So we started out developing lists of things to look at, and eventually turned out into a reviewer guidance.

On March 20th of 1998, there was a Blood Product Advisory Committee meeting, at which point we proposed that the committee sit as a medical devise panel and vote on the classification of BECS. At that BPAC, inspectional findings were reviewed. The device classification process -- since most of the devices are classified through CDRH device panels, we felt it important that our advisory committee understand device classification -- that was reviewed.

We discussed the use of a special control for Blood Establishment Computer Software to allow for the submission of abbreviated 510(k)s. There was a unanimous vote by BPAC to classify BECS as class II devices. And I'm going to discuss the classification process in a few minutes. This vote had the effect of requiring manufacturers of BECS to manufacture under the design

controls of the Quality System Regulation.

It also allowed for submission of special controls with conformance to design controls. After long debates and discussions, in January 21st of 2000, the responses to two citizens' petitions were sent out. One petition came in on March 7, 1996, another came in on January 28, 1997.

Both of them were contesting the fact that Blood Establishment Computer Software was a -- met the definition of a device, and that FDA had the authority to regulate it as such. The citizen -- the response to the citizens' petitions describes completely FDA's rationale and their findings related to the jurisdiction and the authority for us to regulate software as a medical device.

On January 11, 2002, the "General Principles of Software Validation - Final Guidance for Industry and FDA Staff" was published. And it's very important for me to point out at this point that this is a joint document between CDRH and CBER. We had input into previous guidances that CDRH published, but generally it was not recognized as such. You sort of had to note it through the things that were said within the guidance.

This was one of the first software-related guidances were we clearly stated by having both our names present on the coversheet, that this guidance document was a joint effort. Again, it's clearly stated in here that "software that is itself a medical device," and they give us the specific example of blood establishment software to show that we had universal thinking on this.

May 12th of 2005, another joint guidance was published -- the "Guidance for Industry and FDA Staff for the Content of Premarket Submissions for Software Contained in Medical Devices." The title is a bit misleading, because clearly BECS is not contained in a medical device.

So the title is misleading, but the scope does say that it's applicable to those devices which are themselves standalone software. Again, it shows that we are being consistent with CDRH, that this is the FDA's approach to software regulation. On January 3rd of 2007, there was a draft guidance published by CDRH, "Radio-Frequency Wireless Technology in Medical Devices."

As I'm sure you can imagine, wireless devices -- wireless equipment is pervasive. And CDRH was hearing reports of problems with interference, problems with delays

in the signals getting past. So they developed this guidance to assist industry systems and service providers, consultants, FDA staff, and others in the design development and evaluation of RF technology in medical devices.

This guidance references several national and international standards, and discusses some of FDA's regulatory requirements for medical devices, including premarket and post-market requirements under the Quality System Regulation.

Most recently, FDA signaled its confirmation that software can, indeed, be a medical device by publishing a proposed rule in February 8, 2008 -- "Devices: General Hospital and Personal Use Devices; Reclassification of Medical Device Data System," otherwise known as MDDS. This proposed rule recognizes that use of computer-based and software-based products as medical devices has grown exponentially.

Many of you have probably been to the doctor and seen him pull out his PDA to pull up some kind of record, or document some kind of record, and knowing that it had gotten that far, FDA became concerned. They also noted

that interconnectivity and complexity have grown in ways that could not have been predicted in 1989 when the first draft software policy was published.

Growth and expansion have created new considerations for elements of risk that not -- that did not previously exist, but the level of FDA oversight is still directed primarily on the risk to the patient if the software fails. So we're -- our thinking of where the risk lies, and how to regulate according to that risk, has really not changed.

A little bit more about the proposed rule. It describes what an MDDS is, and it recommends classification of them. And much of this text is actually taken directly from the proposed rule. It is available on the Web if you want to pull it down and read the whole thing. But in general, MDDSes are relatively simple devices that transfer, exchange, store, retrieve, display, or convert electronic medical data.

They do not provide any real-time monitoring, alarm detection or display, or diagnostic or clinical decision making. They may be reducing some risks related to manual recording. For example, they'll -- they should

cut down on clerical errors. But they also present new risks because of the lack of transparency and because users tend to rely entirely on an automated system once they have it.

They put all of their trust in the automation, and they tend to believe whatever the device is telling them. In this case, FDA believes that MDDSes can be regulated as class I devices. They believe they're low risk, that there is low risk to the patient, and they also believe that they can be exempt from submission of a 510(k).

So now, as I said, I'll get into regulation in medical devices. The first question we ask when someone says do I need to submit my thing to FDA, the very first question is, is it a medical device? "A medical device is an instrument, apparatus, implement, machine, contrivance" -- just where software fits in -- implement --

(Laughter)

MS. KOCHMAN: -- "implant, in vitro reagent, or other similar or related article, including any component part or accessory which is intended for use and ..." and I've left out a whole bunch of the definition, because it's

like a paragraph long -- intended for use in the diagnosis of disease or other conditions or in the cure, mitigation, treatment, or prevention of disease.

So we believe -- and we believed then and we believe now that software is -- BECS software is a medical device. It's certainly a contrivance, and we believe that one of its main intended uses is to prevent transmission of disease.

Our next question is, is it an interstate commerce or commercial distribution? 510(k) regulations actually apply when a product is for sale or for barter or exchange in interstate commerce. We also consider that the data -- that the software itself may not be in interstate commerce, but the data may be transmitted or accessed across state lines. And so that's another question that we ask.

Now, back again to some ancient history, device classification. Pre-amendments devices are those that were on the market prior to the enactment of the Medical Device Amendments of 1976. Once those amendments were promulgated, we began regulating medical devices. And it was determined that they should be placed into three

classes based on the risk -- class I, class II, and class III.

Class I devices are those devices wherein general controls alone are sufficient to provide reasonable assurance of safety and effectiveness, or it is unclear if general controls alone are sufficient, but the device is not life supporting, life sustaining, or of substantial importance in preventing impairment of human health.

And I've highlighted "not life supporting" and "substantial importance in preventing impairment to human health." And you would rightly ask, but what are "general controls"? That are the controls described by the act establishment registration, here's who I am, product listing, here's what I make, conformance to at the time the act was promulgated.

It was good manufacturing practice, it's -- we now refer to it as the "Quality System Regulation" -- conformance to device labeling requirements, submission of a 510(k) if applicable, and anything else in the act such -- there is other things such as prohibition against misbranding and adulteration.

A little bit more on class I devices. Most of

them are now exempt from their requirement to submit a 510(k), and if for some reason they are not, they are designated as reserved. Most of them are not subject to the design control provisions in a Quality System Regulation. They are subject to the rest of the requirements, and some devices are even exempt from other requirements of the QSR.

These would be the least stringent regulatory category. The most common examples that are given of a class I device are Band-Aids -- excuse me -- adhesive bandages, tongue depressors, things like that. But for this audience, I thought you probably would want more related kind of an example, and in this case that would be blood grouping view boxes.

Class II devices are those where general controls alone are insufficient to provide a reasonable assurance of safety and effectiveness, and there is sufficient information to establish special controls. Special controls are performance standards and/or -- and these are all and/or -- special labeling requirements, guidance documents, recommendations, patient registries, post-market surveillance, other actions deemed appropriate by the

commissioner, and they are in addition to the general controls.

They are generally moderate-risk devices. They may be life supporting or life sustaining, and some have been exempted from the requirement to submit a 510(k). And a good example, I think, for this audience is the automated blood grouping antibody test system. These are class II devices, and they are not exempt from 510(k).

Class III devices are those where there is insufficient information that general or special controls will provide this reasonable assurance of safety and effectiveness. That means there is no predicate. There is not something on the market that the manufacturer can say my device is like or similar to that device.

In addition, the device is life supporting, life sustaining, or of substantial importance in preventing impairment of human health, or it presents a potential unreasonable risk of illness or injury. We handle these under premarket approval, and the manufacturer must submit a PMA. Class IIIs are high-risk devices. They are in the most stringent category and again, general controls apply.

An electromagnetic blood and plasma-warming

device is an example. This slide is too busy for you to read it here, but you can take it away later on and notice that the degree of regulation increases with the increase in the class. And I wanted to quickly go over the differences between regulation of something as equipment versus something as a medical device with BECS in mind.

If it's equipment, FDA is not necessarily going to know anything about the manufacturer, and the users are going to know about some of them, but probably not all of them. If it's a device they'll be registered with FDA, so we're going to know about them, and you have access to the database so that you can find out about them too.

The product is not known to FDA normally, and it is known to some users usually if it's equipment, if it's a device it's listed with FDA. So if you keep going through this list -- and I'm running short on time here -- you'll see that if it's regulated as equipment, the regulatory burden falls on the blood establishment. It does not fall on the manufacturer. It falls on the blood establishment.

If it's regulated as a medical device, the regulatory burden falls on the manufacturer, and FDA has control over it. One thing alluded to was what -- knowing

whether or not regulation has changed things; it's hard to tell. At the 1989 or 1998 BPAC, they've presented data that covered 9 years. They've indicated that there were 16 recalls involving 10 firms.

In getting prepared for this workshop, I reviewed the data from 1999 to the present, which is also almost 9 years. And we have 16 recalls involving 8 firms, but one of the firms had 9 recalls. It's hard to tell; it's hard to really look at these data and know if it's really the same as it was before.

It's highly likely that we have better reporting now, and so there is a better estimate of the effective regulation, and that there was underreporting prior to the BPAC; it's hard to say. So I also looked at medical device reports which are reports of device failures that resulted in death or serious injury, or could have caused death or serious injury.

In the Mod (phonetic) database from 1996 to '98, which is only as far back as it goes and is about 19 months, there were 15 reports or 0.7 reports per month. Since the BPAC, the time period that I covered was 87 months; there were 124 reports or 1.4 reports per month.

But again, we know that the reporting is not always accurate. It's not clear that there is actually a two-fold increase in the number of reports.

I also want to clarify what substantial equivalence is; it's similarity of a new device to one that is or was already legally on the market, or as we call it, the "predicate device." I note I do say "was," it can be a device that was on the market and that the manufacturer took off of the market.

Substantial equivalence is not a determination that a new device is exactly the same as one that is or was already legally on the market and it is not an FDA approval.

What this means is that since there were many different software products with varying features on the market for manufacturers to identify as the predicate device when submissions were first being made, they will continue to be different software products with varying features, unless FDA promulgates performance standards; in other words, a list of required features.

So in conclusion, standalone software can be a medical device. The level of regulation is proportional to

the risks associated with device failure. Regulation as a medical device gives FDA various authorities to intervene, to correct problems, and it reduces the users' responsibilities. Thank you. Don't have time for questions. Probably don't have them.

(Applause)

MR. DODDRIDGE: Thank you, Sheryl. Are there any questions? We do have time for maybe a couple of quick -- we want to try to keep the conference on schedule. But if you have a question at this time, please come to the mike.

(No response.)

MR. DODDRIDGE: I think that's a good foundation for us to continue herein. I think she did a great job. There were no questions, so she answered all of your questions today. Now I'd like to bring up Rodeina Davis, who is the vice-president and chief information officer of the Blood Center of Wisconsin, and the unflappable co-chair of the BECS Conference Planning Committee.

Rodeina is going to describe the winter landscape for blood centers and the drivers and barriers for blood bank IT organizations. Rodeina.

MS. DAVIS: Good morning. First, I want to say

I'm a blood banker first, and IT professional second. It's a pleasure to be here with you to talk to you a little bit about the system choices we have in our industry. And as I really reflected on what to write about here, I wanted to make sure -- can you hear me? All right. Okay, thanks.

As I reflected on what to write, I was thinking during my experience as a blood banker, I had the opportunity really to build the system, and I had opportunity to push a system leading with BECS. So I thought let's talk about what is my experience of being -- using -- whether to build a system or to buy a system.

And in relation, really, to the regulation that Sheryl have explained to us, the objective of my presentation really is to go over the landscape of what's been going on with the technology and where we are with the vendor as of today, to talk my role as an IT professional, and how do I position IT within any organization I work for, share my experience in developing BECS, so prior to and after the regulation, and really examine some inhibitors that as a leader in my organization will be able to deliver the IT solution to really meet the business need.

And those have -- some have to do with the regulation, but many don't have to do with regulation. But I will share some of that with you. Just to reflect back, I feel really privileged and fortunate to work for three great organizations. I was at New York Blood Center from '89 to '92. I also worked at Carter BloodCare, and I'm currently working at the Blood Center of Wisconsin.

During all the -- my tenure in three of the organizations, I had to make decision regarding whether to build or acquire a software or -- and to execute in that decision. Sometimes it's easy to make the decision as a consultant and walk away from it, but when you get the point -- am I still not? I'm sorry.

And then make the decision after that and execute on it, it puts you in a different position as you move forward. Just to -- during my tenure in blood banking, I look at little bit what's happening to the technology. And prior to 1992 -- and some of us still -- probably till now or we still deal with additional implementation wherever we have mainframe application and we use dumb terminal to access the data.

In '92 to 2005, I think we went into the

client/server type of architecture. We started with the fat client and then we moved into the thin client. And I'm assuming everyone know the technology what is it about, but the fat client was basically lots of the logic of the software beside the GD on the PC or on the client versus being on the server.

And when we went to the thin-client architecture, most of the logic was really on the server, and you were able to access it via certain tool that was there, such as Citrix that most of us use over here. As we're looking in 2006 and now, we find more and more we're going into the Web browser application.

And really what we are accessing the data, the text, the images, using -- that are located on a Web page and that's where we are all moving to, that's where we would like to be, the question is how can we get there within the blood banking application.

The future what I see coming in 2000 -- as we're putting our suggestion planning for 2009-2012, we're looking at GD, at rich Internet application where you're either going to be integrating with rich media such as video. We're going to have photo. Web 2.0 is going to be

in. How do we, as an organization, try to fit the new technology into the application to meet the business need?

As I looked at being in blood center and not in transfusion services, I did look at the core functionality when I look at my ERP in a blood center. And I looked at what are the main functionality for the blood center to function, and identified those, because I think we all are aware of them, whether production, laboratory, inventory management, ordering, shipping, billing, donor management, donation management, and recruitment.

That's the basis of what we do in every blood center. We have processes around it, they're all generic processes. We might have some exception here and there, but those are really the core functionality. And as I looked at the vendor that delivered the core functionalities -- so excuse me, some of the vendor, if I didn't list you here.

But I tried to look at the list of the vendor that provide the total solution. As we look at it right now, as you can see, we do have a landscape of vendor that partner with us in our industry, and that they're trying their best to deliver the solution that we need.

We also have many Point-of-Service vendor that complement the existing vendor, that give us something dealing with mobile scheduling, for example, give us something dealing with predictive darning (phonetic), to give us quite a bit of additional functionality but the core functionality are not bad.

And I think which is wonderful, because maybe you don't want to be married to one vendor all the time. The problem become how do I work with these vendor in order to create a data integration. And I think that is the challenge we all face today.

We talked a lot yesterday about the IT positioning and the IT role within an organization, but as an IT leader, I believe my mission and my job is to align the technology and the solution with the organization's strategic objective.

And for me to do that, I need to continuously improve technology, I need to make sure I capitalize on my investment that I did, make sure I would do my ROI, make sure that all the investment I did in one technology, and keep that technology up-to-date so it doesn't become obsolete.

I need to mitigate the business risk while providing disaster recovery, business continuity program, support the growth and enable all the new business offering. We talked yesterday a little bit about the offering that as a blood center we're still not in a competitive mode, we still have to come up with new offering, and we still have to create intimacy between us and our customer whether they are donor or whether hospitals.

And this is the mission -- my mission of my department right now is really to advance the mission of the blood center through high quality services, innovative, and cause effective technology solution. That's the only way I would be able with my team to deliver on the services that my blood center needs.

So a little bit about some of the guiding principle we really use, and really just to provide product and services, as I said, aligned to be able to create knowledge management and offer analytic that would help the executive and the management team make decision, have a standard configuration.

That is very important, to stay up to speed with

the technology, and have a standard configuration in order for us to provide efficient and sustainable operation. And the other thing is, I believe like everyone else, before I started thinking about building an application, the question is there any application on the market that meet 80 percent of the requirement of my organization.

So I have to make -- so help making that decision and provide guidance in that regard. I thought I would share little bit of my experience with New York Blood Center. When I joined New York Blood Center, they were performing over four million tests each year for which they were only entering the negative -- these aren't many. It was what was called the "negative fill (phonetic) system."

I mean -- and their driver to put -- automate that area was quality, compliance, reliability, connectivity, and production course. All the vital testing instrument were not connected to the computers. We used to get list of report, the folks used to take those report. They -- one person would enter only the positive or very active and other person would verify it.

It was the course of doing this and the potential for errors was very high. So I was thinking that was the

time now that -- Sheryl, I'm trying to put your timeline along this timeline. That was the timeline, I think, when they take him up with all the automation on computerized requirement for -- so I remember Dr. Caplan (phonetic) and Dr. Bianco here said we need to do something about this.

So in order to do something, we -- really we had to look hard how to get this done. Software, at that time, was not available on the market really to deal with the volume that New York Blood Center had. They were collecting over 550, importing 250,000 from the European, a total of 750,000 units.

So we didn't have an IT resources' knowledge about a new technology. We had at that time PDP-11, we had excellent IT folks that focusing on that technology. And as we were going to build new system, we needed to partner with someone else to get it done. The problem with when you build, you need the subject matter expert.

And when you -- as we all know, you cannot build with the IT folks. You really need to partner with the subject matter expert. And at that time, we did not have dedicated subject matter expert. And as we started working, we really needed to select -- we pulled people

from the lab in order to work on this. And it was a very good marriage of the subject matter expert and the IT staff to build the system.

And of course when we started that, they have not done a major project like this. We didn't have a business portfolio and project management process, and we needed to import that and put it in place. What did we do about this? We builded a system called Safe Blood that ran for production and laboratory function. Later on NYBC built another system, Safe Donor for donor management and recruitment.

The blood center has invested lots of dollar, lots of amount building excellent system, and I'd be happy to say that Safe Blood was really nominated for the Smithsonian Award and we got the second prize. I think WebMD got first at that time. I don't remember who was the -- but then the FDA introduced the BECS in 1994.

As Sheryl said, none of us knew what the heck that meant, the BECS (inaudible). I mean we were thinking what does it mean for us, what do we do. We had no idea what to do. And I think at that time, as we started getting clearance around 1997, I think that was the time

Sheryl mentioned when a guideline was published.

And during that time, we started all looking at it and evaluating whether -- do we -- do I as a developer need to submit the 510(k). And we really didn't know. So there were lots of question, and I remember talking to some folks at the NYBC and they had some consulting helping them. So the question was what do they make a decision to pursue 510(k) or not.

And they made that decision. It wasn't only -- talking to Jim yesterday, he said it wasn't only the 510(k), it was also the 2(k). So they had to have resources to do both of them. So they have decided at that point -- among other thing, they decided to abandon the development and to acquire a vendor software in 1999.

When I moved to Carter BloodCare, my experience was little bit different, but it was similar issues. The issue with them was the donor management and the manufacturing process, little bit different from what was the need at the New York Blood Center. The driver there was exactly the same, quality compliance, old system, and the interesting problem with that system, it has an operating -- it was a Honeywell that was almost 20 years

old, it had a trigger on the operating system, that trigger would shut down that system within 2 years. And the need for books and the decision on component manufacturing.

So component was a major issue, and we really wanted to look at how to automate the component piece, which is we have not done that when were at New York, that was a totally different thing we were looking at.

Same issue there except New York Blood Center had money. When I joined Carter BloodCare, at that time it was Wadley, and at that time Wadley did not have much money to develop or purchase a system, but it had a problem to deal with it, to stay alive.

So what did we do there? Well, we reviewed the landscape of vendor in 1992 and 1993. It was limited vendor that met our needs, especially in the area of component manufacturing.

So -- but we were fortunate to find someone that really helped us quite a bit in the area of donor management functionality. They really -- we got them in, we were able to partner with them, and within really 6 to 9 months, we were able to put donor management and really get rid of all the compliance problem that we had dealing with

the (inaudible) management piece.

Meanwhile, what we did is to focus on building a lab, a module for production and laboratory to facilitate the books and the decision in component manufacturing and labeling. We completed that in '93 and we did the inventory management ordering and shipping in '95, and then we went back and recreated the donor application to replace our software that we have and that was in 1998.

As you see --during that timeline lots of things was happening with the regulation and we had to make lots of decisions along the way. So again, we needed to make a decision whether to move with the 510(k) clearance.

I think Sheryl brought up something here, which she did it with -- it was an interesting. You determine it's a medical device, then you need to determine whether it is medical device class II, and whether there is anything across -- to go across, intercommerce state or data going across.

So I think the decision -- when I was thinking about -- as you were talking about this, in New York Blood Center they were doing business in both New Jersey as well as New York. So definitely there is an intercommerce

playing here. When we were in -- at Carter BloodCare, the question is do we need to do 510(k).

Well, we were doing a lot of testing across or someone else -- we were doing testing for someone else. So the question is, is that a 510(k) or not. I mean, it was -- we're not selling the product, we're treating the product internally. I think those are good questions to ask today and to have a dialogue around it.

If I'm going to develop my system for myself, and I'm using it to receive data or to send data, is that really a medical device class II? I mean, those are good discussion to have today.

So you can see here, we learned a lot with the lab module. We became an expert after that. I think with the distribution, we went to abbreviated 510(k), took a 6-month, then with the donor, we got that thing is three months. It was wonderful, we celebrated for that.

But I think it was a very interesting experience, and I'll talk a little bit about it later -- but I think what happened with that at Carter BloodCare, the cost of owning the software as well as to sustain 510(k) because what we believe, and maybe I was wrong, I always believe in

high quality system and regulation in my shop, we really had a separate function doing nothing and I said have it now in my -- in every organization code, I ask quality.

And we had a large group and I asked quality that do we need documentation, validation, training, overseeing, auditing, everything we do. So we have to build additional layers in top of what's there, but in this case for the 510(k) instead of having four people, we had seven people. And did I need the seven people at the time? I don't know, but I felt I needed to because I didn't know much of what the regulations are.

I mean, those are the type of discussion we need to talk about, and we really now are much more sophisticated of understanding the requirement of what do we need to do to sustain it than we did at the time.

But as you can see, because of IT, it has pushed beyond 8 percent. To give you an example, my cost, right now, of IT at the Blood Center of Wisconsin, is 6.5 percent. The averages go between 4 and 7. Mine is high right now because we are in the middle of implementing many new applications, adding lots of new functionality. But I would see in blood banking to be around 5 percent.

I think we have lots of discussion at the board level as well as the executive level, and we all decided we could not sustain the cost. So we, the Blood Center marketed, and I become a marketeer and a sales person to try to sell the software for a while. But we ended up selling the software in 1999 to a commercial vendor.

I think this is a picture of my lab submission when we submitted the lab there. And look at the picture, I aged quite a bit from 15 years ago probably, but what I'm pointing here, because we really didn't know what we were doing we submitted over 36 binders to the FDA, and I remember Dr. Jay Epstein calling Dr. Murrow (phonetic) and said, "What the heck are you guys doing?"

And I think maybe -- after looking at everything there, maybe you guys decided maybe let's get rid of all this, let's go for the abbreviated 510(k), after looking at the number of volume we submitted down to them. But it is an education because at that time that was right when the publication started coming out. So we really did not have a chance to understand what's needed. So we took everything we have in the file cabinet and we copied it and we sent it to the FDA.

In my third experience going to Blood Center of Wisconsin I figured out, got a chance to develop two system, got a chance to put 510(k), got a chance to make sure -- the organization could not support them, I better learn from my lesson. And let's talk about little bit what's going on and what happened at Blood Center of Wisconsin.

The issue remained the same with every blood center when you let your system go down. I mean, we had issues that are similar to what Carter BloodCare has similar to what New York Blood Center had. There were systems, HP 3000, they have not been upgraded for over 10 years, 12 years, so we needed to do something right away for them.

And at Blood Center, we are not only a blood -- we have our blood services arm, but we have also the diagnostic laboratory that needed all system as well. So when we started there with the -- trying to look at system, the first thing we said, we're not building, we're buying.

And we replaced our core system for the blood bank and the diagnostic lab in the first 3 years. Then we started really at that point -- we were talking little bit

yesterday about how do we mature IT within an organization. And we started working very closely in developing part of the strategic plan -- organization strategic plan, develop the IT strategic plan.

Our first IT strategic plan that we developed after we did the upgrade is really, I called it the "phase of solidifying." And really what we needed to do is to take every system we have and replace every system. So we upgraded the infrastructure, we look at the process, we look at the service we provide, the quality, and the people.

We brought a brand new team and we upgraded the team -- the technical ability of the team we have. We really worked very hard; we were introduced to ITEL as a framework for providing service management. We worked very hard on that, and as we moved through 2006 to 2008, as per our strategic initiative, the thing here was to really extending, going away from what core application is and to add value.

And as we speak, I'm completing my 2009-2011, and I'm calling that phase of our strategic plan as "transforming," really how to use the technology to enable

business transformation. And I think I feel very strongly that's where we need to be and the question is what are my challenge to get there.

Just a little bit -- this is what I'm working with as my strategic plan into the digital age in our healthcare sector. My boss, my CEO want a Web 2.0 right away. I needed to implement Web 2.0, social networking, PC University (phonetic) education collaboration. So we need to work on looking at the relationship with using the latest technology with the hospital customer, donor, and donor-sponsor, and really knowledge management.

I'm going into knowledge management because with the Web 2.0 it's going to give you the tool and the capability, to help create that knowledge management internally as well as externally. Technology we're looking at RFID, you heard enough about this, YMS, and I'm glad that we now -- we have some guidance around it and that's helping us moving into that area.

We -- I think maybe toward 2011, we'd be looking at voice recognition, but bandwidth is a large thing now. We're starting upgrading all the bandwidth in our network to allow us to do the technology we need. Data

warehousing, data mining, electronic medical record, and being -- supporting a large resource institution we are looking into large patient and biorepository databases. And of course, we're all dealing with the security issue when you deal with all the new technology.

I thought I'll share with you a little bit what is our enterprise architecture. The way I see it for the blood center, our blood center and other blood center, and I'm going to share with you the issue we have with getting there. So this is my BECS, this is everyone's BECS, donor management, donation management, laboratory, distribution, production, recruitment, and how are we going to manage all that.

So first -- this is the basic. We have established the basic; let's look what we need to add to it right now. As I look at that, the second area we went into it, on looking at is really the recruitment software, the code-tracking software, device scheduling software, device coordinator, and the CRM software. So when I was talking about those, in that system these are key to the success of our operation.

And we need to have these software, and guess

what? We need to have these software to talk to our BECS, because as I schedule an appointment, I need it to schedule -- look at the BECS and schedule the appointment, whether that person is eligible to donate, when that person is eligible to donate, how is that person and when I'm going to call him, what kind of procedure I'm going to ask him to do.

So there is quite a bit here of think just how I'm going to create the data integration between these areas. And as I look at it, we added now automated health history and phlebotomy capture. So previously, and we're still doing that because we are in final phase with this, what we do right now, we ask the question out in some piece of paper, everyone answer it, then we review it, we take the answer that we need to put it -- data entry staff enter it into your system.

Well, now we are really very sophisticated. We are asking the donor to answer all these questions online; they'll answer it, enter all the information, we print the VDR. We print it, we take that printout and we go and we give it to the data entry, and they enter it again. Where is the error? I'm creating two places for errors.

So how do I think about streamlining the process, how do I make sure that my data is correct? The quality of the data that's coming in between once it get in, why can't I move it all the way along? Another area we've looking and working on is what we call community inventory network.

We were talking about that little bit yesterday about the ability to really create transparency between us and our customer. We are looking at order management, community inventory management, not only what's in the blood center, but what is in our community, what every hospital has. Can we see it? Can we create data transparency across the whole system?

Looking at the area of demand planning, what is the demand planning? What is our production planning based on the demand planning, and can we create forecasting? A very similar thing, every manufacturer does -- is their ERP, basic ERP, can we forecast what do we need to produce for the coming 6 months? Can we forecast what we need to do for the coming week? I mean, this is the question we face all of us together.

Analytic -- and I cannot say much about it because we're talking a lot about data mode, data

warehousing, try to visualize and try to search and mine data and come up with the solution. So this is the area we're building like now. If I look at everything you see here, this is -- most of this is done. We are in the process of now thinking, our next year looking at demand planning and forecasting, this year we're finalizing the inventory management and the order management piece. And we have put the data mode and data warehousing last time.

So collaboration portal for hospital and sponsor, Web 2.0, we will add those. Order replenishment -- well, every manufacturer had, with the details, have order replenishment, so we will want to do that. This is what we are going to add.

And to streamline everything, we want to add the RFID to our supply stream in order to make sure that we improve our processing and to increase the safety of the patient at the transfusion services. So well, how do I do this? I need something. I need a gateway, I need data integration. I need a way to talk -- these system to talk to each other.

And this has been really my critical, the most critical piece. And I don't know who to talk to, whether

it's the vendor, whether it's the regulation, or whether it's us as an industry, not understanding what's BECS regulation is all about.

And I'm hoping in this session today and tomorrow, we get to some better understanding, what is my responsibility versus what is the vendor responsibility in integrating the data. I think, when I look at -- the challenge I have, to deliver the solution that is expected of me as a leader is really to look at interoperability and to look at the access of the new technology.

And really the question is we don't have a standard for data exchange and blood banking. I need a way to get this data across. Do I have the right to go into BECS' regulation system, and update the data. It's my data. The data belong to the Blood Center. It does not belong to the vendor.

Where does BECS' stop, the creation stop? I mean, I talked to vendor and said you cannot touch those data. It's my -- it's a closed system. Otherwise we had to go to the FDA. Where is the line there? I mean, we need to have better understanding. The same go with the access to the new technology.

Our existing BECS software are not up -- current with the new -- with the existing technology, and to invest a new technology, it is going to be very expensive for them.

So this is where I am with my conclusion after I thought about it. Following proven software development life cycle, as we all know, I think we end up -- really connect with the system that provide quality software, that include all safety critical function.

I would say the system we developed or the system we did before the BECS or after the BECS, both of them had the exact same quality product at the end deliverable with it. I really think we can do better with -- when we look at -- try to translate the medical device requirement and try to associate those through the software development.

We all have major -- it took a long time to figure it out. As a matter of fact, we had a loyal office staff to help us figure out how to translate what we were doing and the SCLC (phonetic) to what the -- really the 820 it's telling us to do.

I really think the hazard analysis methodology under the BECS regulation is more applicable to blood

banking software than any others. If I like anything about the whole 820, I like that hazard analysis because it really force you to come up with true labeling of the product, so the user can understand what is controlled within the system, and what is not -- what else you need to control via your SOPs. And I think that's key for us, and we'd like to adopt it; as a matter of fact, I adopted in my methodology right now when we developed system.

BECS regulation to me, it's more guiding a less experienced development house to have quality process in place. If I am an expert developer, it -- I think it's in line of what I'm doing, it's not adding much volume to me as a developer, it's making sure I have documented the process.

I'll follow the process, I document the deliverables for SCLC, but this is -- really tell us little bit more about, you know, if you want to remember what happened, you know it.

Wrapping up, I think perspective on value from the BECS regulation is different among the stakeholder. We must balance it and reconcile it for us to do a win-win. I don't think we can transform forward the value unless we

know what work and what doesn't work. I think Sheryl tried to share some metric with us this morning, but I hope you can come up with more input on that.

And I really hope that this workshop will create dialogue for us all. The idea is to be able to promote quality system, but at the same time meet our business objective here.

Thank you very much.

(Applause)

MR. DODDRIDGE: Thank you, Rodeina. I think that one slide said it all. We have our basic system and with everything we have to integrate outside, that's the whole question we're trying to answer today.

Are there any questions to Rodeina? If you -- please go to the mike, if you do. I think it's just great, our speakers are really presenting the material and everybody is understanding it today. Thank you.

Our next speaker will bring a vendor perspective, as Marsha Senter is a product manager of LifeTrak at Mediware. She has been with Mediware since 1999 but she has much longer history in her focus on multiple 510(k) submissions, for both donor and transfusion systems. She

will discuss the pros and cons of the 510(k) clearance.

Marsha?

MS. SENTER: Good morning, everyone. Can you hear me okay? Okay. Now, can you hear me? Can you hear me now?

Hi, I'm Marsha Senter, and I'm very excited to be here this morning among all of these distinguished speakers. Most of you do not know me. So I'm going to give you a little bit of my background.

I'm a med tech. I was the subject -- one of the subject matter experts that Rodeina had when she developed the LifeTrak System. Since then she introduced me to the IT arena. I've been sitting there for 16 years.

Not just sitting, we've been moving along quite a bit. Moved from quality assurance to regulatory affairs and now I've gone back as someone said to the "dark side." I'm in product management.

My objectives this morning were to -- are to describe the evolution of our submission process, and identify the impacts that we had, hurdles and horizons that we had to get over and things that we see for the future. And I want to discuss the class and status that cleared

BECS.

In the early days of the 510(k) -- 1994 was the decision point for several vendors who were out there, some of them just folding in and saying we are not able to more forward. And that continued on for several years.

So that did stick it out and manage had a lot of work ahead of them, and it was a long and tedious road, not just for the vendors but -- I not in the vendor arena at that time, I was at the Blood Center, Carter BloodCare, and the other -- the users have the system. So we were working with FDA.

FDA was -- we were all in a learning position. FDA was new with this, and so were we. The learning experience was quite unique. It was a hit-and-miss for both sides for a long time.

We had consultants. Most of those consultants were from previous FDAs. We had meetings with FDA, people were going to Washington, there were conference calls, everything was going on back and forth, and some of the discussions got pretty heated and some of them were not.

Sometimes we were just at a loss as what do we need to do next. Rodeina stated it very well. We just

didn't know how to deal with this, it was something very new to all of us. The documents that we got from FDA at the time, they were pretty lacking. There was no cohesive guidance initially when we went in. They've improved quite a bit, but still having something that is specifically for BECS, for software, has been an issue over the years.

Our first-time experience, it was very timely. We actually submitted -- our first experience with it, with LifeTrak, was the submission of 510(k) that we inherited back from a company that decided they were not going to pursue it. So we got back, well, I think it was one binder. Rodeina said it was two binders that were the entire submission. You saw the picture of what we ended up submitting after about a year-and-a-half of discussions with FDA. Our first initial submission was 26 binders.

You have to submit them in triplicate. So Rodeina had a pretty good sized office which had paperwork spread all over the floor sorting out documentation, making sure it was correct. We labeled these binders meticulously, only to find out when they got to FDA, they dumped them out of those binders and rebound them.

We didn't know that at the time. So we spent a

lot of money on binders, we spent a lot of money on doing this beautiful presentation, to find out it was set by the wayside, the review was never looked at. It was very organized. After all was set and done with many conference calls going back and forth, many, many hours on redoing things, the -- we actually felt like going in. We were doing it correct.

We felt like we had accomplished quite a bit during that time. The testing that we did, Rodeina was actually very active in developing testing protocols, working with a validation process. We felt like we had done a good job. And today, I still feel like we had done a very good job except that there was a couple of a thing at the time that FDA didn't like, so we had to redo some items.

It was fairly objectionable, but when you say you have to do it, you have to do it. We submitted it and went on. We got our first letter back saying, well, we want you to do a few other things, so by the time we submitted that, it was seven more additional binders, all bound nicely and neatly, again, all in triplicate, which we had to keep the copy of the binders back at our facility to go over and

understand what they're looking at when they call us and give us a question. So again, that was a lot of time and a lot of effort for something that was tossed.

So, do it right, do it wrong, we didn't know; FDA, at the time, really didn't know. We were going back and forth again. We've reviewed everything that our system did, in and out, upside down, backwards and forwards. The information that FDA got, we felt like it was very significant.

It was the validation part of it that really kind of threw us because again, like I said, we felt like we did a very good job on it. They had some questions, so we had to add additional information for that. Perspectives, part of the initial problem was the "substantial equivalence." We were kind of at a loss for what did they mean by "substantial equivalence."

We had to claim conformance to a product that was in the market prior to, I believe, it was 1976. Going back that far, trying to find a computer system that is equivalent to what you're doing today, 20 years earlier was very difficult to do.

Basically, FDA told us at that point, we don't

care if you're building a Cadillac or Volkswagen. We want you to tell us how you're building it and exactly what you're doing. Finally sunk in we got it. One day, after all of this was going on, there's a moment of silence from FDA where you really don't hear anything, and you're going okay, is it good, is it bad, what is it?

We got a phone call out of blue, saying you're cleared. If I had -- if I could backflips down the hall, that's what I would have done. But I was so excited at that time, and we felt like it was a real accomplishment and it was a two-year period.

Mediware's first -- I was not with Mediware at the time, I went to Mediware in 1999 -- but Mediware's first 510(k), their system was a transfusion system, and it was fully entrenched in multiple facilities. There was a great lack of software, availability of software for transfusions at that time.

They decided that they were going to go ahead and move forward. They looked at what needed to be done, again, quite a bit of expenses and consultants. They did several visits to FDA, conference calls. It was time-consuming; their experience was much like ours on a little

bit different level, and they did receive their clearance. But it was pretty much the same game and I think it was like that for most people who were submitting during that time. And again theirs took just about 2 years.

Moving ahead, the picture showed it all. We had all those volumes of binders and that was just one set. Put it in triplicate, the cost of mailing that was unbelievable. Along came the abbreviated 510(k) which was wonderful. It let us claim adherence to a special control which was the reviewer guidance that was published in 1997.

I actually liked that document quite a bit. It gave us a template for other documents to be used, which -- the hazard analysis we still use today. And there is not a lot of templates out there that are available for use.

But this one, Rodeina actually said they still use it, it was identified a hazard, what causes it, level of concern, likelihood of occurrence, your method of control, your trace to your designed document, your requirements, and now there's another field in there of your trace to your validation. And this is a key document. This little template saved us hours and hours of agony and

it was just one little line in this document. They had another template for functional requirements.

It would be very helpful to us today if we had more of these type of templates available, simply because it's -- you can put forth the document, you don't know if it's right; you can ask for input -- they can give you certain -- they can give you information, but they don't have templates or anything like that that's readily available to tell you, this is what our expectation is, to see -- but we also need templates that are not just for presentation-type documents to FDA. These need to be viable working templates that are utilized functionally within your center. This one actually is very good and it's utilized.

The 510(k) relief with the abbreviated 510(k) was wonderful. It was much less volumes. I think our first abbreviated 510(k) either had seven or nine volumes, took much less time to construct it, we only used up about half our office instead of the entire floor.

Cost savings was immense, but again we still did not know about the binder policy or they take everything out of the notebooks. It was much easier to manage, the

submission was easier, there was a lot less to review. It basically contained documents that were required in a hazard analysis. We did not have to submit our validation at the time, we had to submit your alpha test -- your test plans and your testing summary which were utilized for the validation. And there are other documents that are required in there, but they are less -- you are labeling for one thing, all of your user documentation which we have quite a bit of.

So it made it a lot easier to submit. We made sure, it was very organized. If we wanted to look at it and find something -- we had to make sure that the paper trail, which is all FDA really has to go on, the paper trail is easy to follow.

So in this same review time period -- but looking at 26 or 35 binders within 90 days versus 7 binders within 90 days is a significant decrease in the amount of time and frustration that's been on it.

There were several FDA documents, one of then which is still in effect today, and I find this document very difficult for us as BECS, it's deciding when to submit a 510(k), for a change to an existing device. This

document is not meant for software. It is not meant for anything like BECS. Actually, it's probably very easy to go utilize that document and say, I don't need to submit or I do need to submit, based on how you want to steer your information.

The new 510(k) paradigm also gave us more information, but exactly did not fit to BECS. None of these documents actually fitted for a BECS. The closest thing that came to it was this guidance for the content of pre-market submission for software contained in medical devices. Except it had a disclaimer in it, not it's a draft policy for standalone software was yet to be developed, the entire document, and that's what stuck out. So we were still kind of at loss on what we need to do with this document. So still, limited specificity for BECS.

Ambiguity -- we are using documents that are geared for a true production line. You've got a widget going on the line and a widget coming off and it's got some software in it. That was the best that we had.

The real value in these documents would be, we really need to know what you need to have presented to you, but it also has to be a document that's truly utilized in

the blood center or in the development arena at your vendor area.

It's very difficult for newcomers, those who have never submitted before to pick up all of this and look at it and know what to do. It would be -- I would never be able to do it on my own, it's a conglomeration of things that you need to know and it would be very hard for a, like I said, a newcomer coming in, to try to know what to submit for a BECS clearance.

FDA is now doing collaborative documents with CDRH, I mean CBER is doing the collaborative documents with CDRH. And this one that came out in '05 or the guidance for the content of pre-market submissions for software, it actually moved us back to more volumes for submission, not nearly as much as the initial 510(k) process, but it's much more documentation than what the abbreviated is. We lost our special control with that, the guidance that was for 1997, the reviewer guidance that we couldn't submit under that any longer.

It clearly states in this document, here is what you need to do. BECS is outlined very strongly in that. So there is no question, and it does help guide you in the

type of document you want submitted. Part of that was I ended -- as soon as I read it I called the FDA and I said, "What is this revision history document you're talking about," and a part of it is just terminology, understanding the terminology on what they're talking about and the terminology on what you're using.

We happened to use a piece of software for that revision history where we keep track of all of our past and failed test cases, that type of history and this was basically a benchmark of where you were at different phases of your validation process. So instead of us keeping it basically in our software, we now had to pull it out and map it out in a document that's going to be presented to FDA.

So part of this is a better understanding of the terminology in the documents and we need a means for proof, such as things that are kept in an automated system that we use internally for our quality system regulation process controls versus documents that have to be sent to FDA. And we understand the need to ease the burden, so it's a large burden on the vendor, on the blood bank community, as well as on FDA, going back and forth trying to decide or

decipher what all of these information, how it needs to be presented, and what the information is.

The FDA has always been very willing and very cooperative with me when I was at the blood center and also with Mediware. We have a very nice working relationship and they've been very helpful. I've never hesitated to make FDA our friend on questions that we need answered and they've been very, very helpful with this.

The hurdles that we found is, I think there is a fear of submission among many companies. They just -- they don't want to have to ask FDA anything. They feel like if they have to ask FDA, FDA is going to tell them yes, you have to do it. That's not the case. I have found that, that's not necessarily the answer you're always going to get. So I do not abide by this don't-ask-don't-tell type situation.

They limit the movement for smaller companies to move into this arena because they don't know what they have to do and the larger companies too who just say, I don't want to deal with the submission process.

So what do we submit? Part of it boils down to are these presentation documents that FDA wants to see or

are they real buyable documents that are usable within your facility. It's a hard line sometime to make that distinction. I've had development staff, I would give them a document and they'll look at it and go, but this is not what I'm used to, it's not giving me the instructions that I need.

So to make these documents more easier, friendlier to use, they have to be something that is not presentation format for FDA, something that is a real usable document, real world applicability.

It would be nice for these 510(k) submissions, if we had more formats and examples of what needed to be submitted. There was an open forum, and especially in places like this where we could meet with FDA, talk about the development process and talk about the things that we need for them and the things that we can supply to them that is mutually beneficial to us both.

Expectations currently are that everybody does what they're supposed to do. Most people do what they're supposed to do. There are -- we would have no 483s, no vendors would ever have a 483 if we always did exactly what we were supposed to do.

Same in the blood industry; a donor's in our transfusion service, -- no one would have a 483 if we knew exactly and follow what we were supposed to do all the time. So the expectation is that, yes, we all make mistakes, but we want to have a better process, a better control for moving forward.

The whole caution or the whole reason for going to a BECS is so we can make that process move forward and have a better transfusion or donor software, plasma center also.

Hurdles -- again the time -- the preparation time for making these submissions. You basically are printing off volumes and volumes of documents that you already have.

Electronic signature -- some people have a hybrid system where you're still using a manual signature not electronic signature to do your documentation. So just printing those documents all is not always the thing you can do, you have to do scan copies which makes it a little more timely.

The binding process -- we found out not until 2002 that the --we were not supposed to submit in all of these notebooks. That made it much less expensive for us

and easier to do. They just use those cardboard binders that you buy at office depot or something, they're the heavy duty binders, and label those. And it did make a big difference and how long it took to bind it and having readily available the supplies that you needed.

It also could cause a delay in our review time, the binding alone, because when they would receive these in at FDA, before they ever got the Reviewer's Office, they were taking them out of the binders and rebinding them which left a very uncomfortable feeling in my stomach, because I know we worked very hard to get these in the exact, perfect, right order and if one of them were dropped or something, basically our submission could be held up several days just because we were trying to reorganize.

I'm going too slow. The cost of the actual submission of those volumes of documentation in triplicate, in-house volumes that we had to keep, I traveled quite a bit so I had a volume that I had to keep in Chicago and a volume that I had to keep in Dallas. So we didn't do three volumes, we had to do five volumes.

Other hurdles were reviewer resources. That office has a limited amount of resources anyway for the

amount of the work that they have and then the training time for the reviewers was quite a long process. So sometimes you would get a reviewer in there who had to have a more senior person with them just to get you through your review process.

The consistency -- we would submit a 510(k) and it would be perfectly cleared and then the next time we would submit it we would miss a document out of it, but it was document that wasn't in the previous one and most of these ended up being forms that were required by FDA that we didn't know about previously. And I don't know if we just missed them or if FDA missed them when they did the review process.

The pace of movement -- it's slow by design. There's nothing we can do about that currently. We're here today to see if we can speed up the process. The documentation again is lacking as far as specificity for BECS, it is getting better. Technology is moving ahead so quickly that the review process and submission of these BECS preclude the ability to move that technology forward in the blood centers and the expectations of industries is

that we're going to stay up and meet their demands and meet their needs.

Technology changes -- again, rapidly evolving, innovation, ability to keep pace and they're very difficult for us in the vendor arena. The user community is ever evolving, we need to be able to be quickly responsive to them and they have struggles in the industry, the struggles to meet the demands of their blood supply, the struggles to meet their, development of their internal processes as far as moving out and spreading their wings to develop further business.

Horizons -- we need do fear abatement as far as FDA. They're our friend, they're not our foe, now they have an interactive review process, which we always made it an interactive review process, and we kept the lines of communication open.

Our focus here today is to help them help us. Conferences like this are very important. This is the first of its kind and I'm very honored to be here and I think this will help us move forward and let them understand as a community, a community of users and

vendors, what we need to do to help us keep up with the technology changes.

Collaborative documents -- there is an industry document out there, it was published I believe, in 2003 and it's the ISBT document for guidelines, for validation and maintaining the validation state of automated systems in blood banking.

I'll speed it up. It's a very important document -- he's given me the go ahead. We need to remove the confusion around BECS submission. Specific documentation, frequency, and updating of the 510(k) remain timely to technology changes. This is all hard to put into one package, but a lot of us don't know exactly when to update the 510(k) or how frequent to do it.

We need examples. We need to be appraised of the status throughout the process of our 510(k). If we could log on to a system somewhere and find out here's your status, know where we are, what type of review, what's missing, that would be very nice, and enhance the clearance notification process.

I found out that you do all of this work to get cleared and then they send you out a letter -- I believe it

was third class mail? Third class mail. So that's not as responsive as I would like for them be.

(Laughter)

MS. SENTER: Technology in the submission process -- we are looking at possibly online -- if we are going to maintain this online submissions, electronic documents, it would save a lot of time, reduce cost, reduce errors on our part, binding all of those documents, ease the burden and accessibility suit submissions.

There's a paradigm shift, this is apparent -- and I'm going to breeze through these real quickly -- this is apparent of our paradigm shift and we need to enhance these processes. I'm not even going to go through that one. I'll skip that.

Why are we here? We know it's a criticality of the device, but there's other devices out there other software that's just as critical if it's not treated as a device.

Validation -- all of us have learned from the validation processes. What happens is less than expected validate in-house or less than expected validate in-house, the community blood centers do a lot of in-house

validation. When you get to the hospital-based validation that's a higher volume of outsourcing. Many use third party and many depend on the vendor. Validation services are flourishing today, flourishing.

Here is a little stats, it'll be last slide. There a 116 cleared BECS, 42 percent of them were cleared before the year 2000, 36 percent of the clearances are held by four vendors today, 64 percent clearances are held by 41 vendors, 18 percent have one clearance and only 6 percent of those were cleared before the year 2000.

Thank you.

(Applause)

MR. DODDRIDGE: Thank you Marsha. I'm assuming -- Marsha's assuming there is no questions for her, so -- but she'll be around during break if you need to ask her a question.

We're going to take a 10 minute break and try to be as -- I have 20 after about, is that correct. So we'll try to be back here by 10:30.

(Recess)

(Discussion off the record)

MR. DODDRIDGE: We'd like to stay on time, so if you'd please take your seats we'll try to get started. I don't have my gavel like I have at Rotary, but I'd like go ahead and get started here. Our next speaker is Linda Weir, Linda is the FDA's expert on the regulations of BECS. She is going to describe in more detail the 510(k) process including turnaround times and the differences between software used in blood centers and transfusion centers and I think what I heard her just -- with Alan talking to her, she's got a couple of updates that she has learned during those first few presentations. So without further ado Linda would you come forward?

(Applause)

MS. WEIR: Okay, I have a question. How many in here know you might find me by voice?

(Laughter)

MS. WEIR: Okay, same here, so come up and introduce yourself during lunch or something, so I can match a face to the voice.

The mike -- can you hear me now? I'm afraid to touch it. He has so much -- can you hear me now? Okay good.

These were the topics I'm actually going to discuss, no matter what this gentleman said. And having listened to the previous two submissions, I'm going to add some to it, because I think this conference actually is going to be very valuable for both of us, because I've identified some more common misconceptions from Rodeina especially, and even from you, that hopefully I can clear up. And we need to identify a better way, I think, to get these out to you so that we don't have to you know, spend all this money to come here for us to tell you.

But I have planned on talking about the documents FDA request in the 510(k), why we request these documents, frequently encountered problems in the 510(k) process briefly, the fact that innovation and regulations are not incompatible and common misconceptions which has grown exponentially since I got here.

The documents that we request are those recommended -- okay, can you hear me now -- okay, are those recommended in the guidance that she mentioned unfavorably --

(Laughter)

MS. WEIR: -- guidance for the content of pre-market submissions for software contained in medical devices issued on May 11, 2005. It's used for software embedded in medical devices such as instruments as well as for standalone software such as BECS and I have to be honest with you, every software that's reviewed in the agency, if it's a device embedded, if it's embedded in the device or if it is a device in itself is reviewed under this guidance.

It was developed by CDRH and CBER, I actually sat on the committee that wrote the guidance, because we believe FDA should be consistent across centers and what we asked to see in 510(k)s were similar type of submissions such as software.

And to tell you the truth, I hate to tell you, if we issue the guidance document specific for BECS which we may be doing after this conference, it would be this guidance with the omission of data recommended for minor or moderate level of concern which we will get into lately.

However I feel the level-of-concern information contained at the beginning of this guidance is valuable for

you to understand why we consider BECS to be a major level-of-concern device.

The recommended documentation depends on the level of concern of the device. There are three levels minor, major, moderate, depending on risk. BECS has been determined to be a major level-of-concern device. We asked for the software description, software requirements specs, architectural diagram or design, software design specifications, traceability analysis, hazard analysis, the description of the software development environment, verification validation and testing, a revision level history which some people thought was all of their bills, every single bill they did. And what we meant was just those that we released, you know, to your customers, we didn't want the detail of the bills.

And any unresolved anomalies which are commonly known as bugs and limitations of the software. Who knows the difference between a limitation and a bug? That's a common question too. The really simple answer is limitation is built into the software, you meant it to work that way. Like you meant not include electronic crossmatch.

If it's something you didn't mean to happen but it happened that is the software defect or bug. So a limitation is something that you -- someone might think your software does, but it doesn't.

I had a conversation with a gentleman one time. He was arguing, the word "bug" or "defect" has a bad connotation that these -- his list of limitations were not bugs, and I said, "Well, let me ask you, did you design your software to do this?" And he said no.

(Laughter)

MS. WEIR: I said, "Okay, that's a bug," and if you do submit the list of limitations or the defects, I mean, you should tell us the work around and give us some sort of timeframe of when you're going to fix it.

You don't have to -- it's not firm, but give us an idea of what your plans are. The reason we request these documents is we believe that if you're doing good software quality engineering, these are mostly going to be an exercise in photocopying and to speak to what our last speaker said, I actually prefer to get the real working documents.

When I get things that are obviously setup, you

know, just for FDA it makes me question what are they doing and how -- because this is just what we really want to know, and I think we've evolved over the years in learning this at FDA and I had rather call you and help you -- help me learn to navigate through these documents and I know they're what you're really using.

The whole idea of using this guidance was to -- these should be documents, we felt, that you would have in your development and could just submit to us.

We had two -- actually three, since this was written, success stories and don't anyone in here feel bad, if you're not one of them. Recently we received two 510(K). Both were from firms who had never submitted a 510(K). One was from a firm who had not even requested pre-submittal support and it contained wireless technology.

The second one fell from the skies. We said, we'd never heard of the company, didn't know what they were doing, it came in, I said, oh, my gosh, you know, it's going to be a mess and it wasn't.

And they both received one minor additional information letter and were cleared. They told me they had followed the recommendations in the guidance and were

successful.

The following slides will compare the documents requested in FDA 510(K) for BECS to those contained in the American Society for Quality Software Division Body of Knowledge, and if you're not familiar with ASQ they have various exams you can sit for to be certified in various areas and each of their areas will have topics that will be covered on the exam, and that is where they expect you to be expert on in order to pass the exam.

And I chose these rather than other standards for simplicity only and of course FDA is not specifically endorsing the ASQ recommendations.

The left column obviously is what we request in the 510(K) and the right column is ASQ. I'm not going really go through these in detail, but if you read through them, you'll see the terminology may change a little, but they are basically the same documents.

I'm looking to see if we see any differences here. (Inaudible) have more detail under verification, validation testing, test planning and design, test coverage, test plans, test implementation, test documentation, test report. They also want -- they stress

defect tracking and the severity of the anomalies, which we did too.

Now, to get to some frequently encountered problems, probably the most frequent problem we get in a 510(K), and often leads to AI letters or worse, is the quality hazard analysis.

Not in the format that it comes in, but in -- in particular identifying the cause of a hazard as the hazard. An example would be identifying the hazard as mistyping the patient's blood, when the actual hazard would be the patient receives incompatible blood with the potential cause being mistyping the recipient's blood, and note that hazards can have multiple potential causes.

Also the inability to trace forward and backward between requirements, detailed design, hazard analysis and testing. We have more and more problems with that as we've used automated tools to track these things.

What we found ourselves lately doing sometimes is actually calling you, because these things are online with you, and you can just go back and forth and zip, and help us find it.

You know we get -- the biggest 510(K), the

largest was a 180 volumes. The typical one now is probably between 20 and 30, and I hate to break it to you, we don't read all the 160 volumes. So what we do is we look at the hazard analysis or the requirements and pick out some high risk areas that we do want to look at it in more detail and we depend on your traceability analysis to help us navigate and see if that hazard was mitigated, did you test it, and the mitigation worked.

So that's why it's important to us, the forward and backward. It's important for you, the vendor, those of you who are. It's because if you detect a defect in a certain stage of development, you need to be able to locate where the defect was injected and correct all other stages that might be affected by the defect and as you're all well aware, the earlier you can pickup a defect, the less costly it is in rework.

Also your requirements documentation, as you also know -- probably know, should be written from your requirements and you need to be able to trace the requirements to your testing to make sure all of your requirements have been tested.

Now the most frequent cause of -- not

substantially equivalent are NSC, it's the easy thing to say too many software anomalies or bugs, but the few of you who may have gotten the letter didn't say that you've got too many bugs, bad software.

It probably said that you had -- did not submit performance data -- enough performance data, or that you had failed to consider the modifications you had made to your software and considered the impact they would have on the device, the safety and effectiveness, but this all leads to too many software anomalies or bugs and I say that because the fear that we have, NSC had a lot of software anomalies and bugs as well as problems in these other areas. So in other words you're going to get bad software.

In 9 years, since I have been there, CBER has found only three BECS submissions to be not substantially equivalent. All of them have more than 200 software anomalies or bugs, and in all cases the applicant corrected most of the anomalies, resubmitted the 510(K), and were determined to be SCENARIO (phonetic).

We tried to work with you as much as possible to prevent this happening and if I can go back to pre-submittal support, we do offer that, those of you who

aren't aware, Marsha is obviously.

We find it easier to do the work upfront than afterwards, so that when we get the submission in, we've got something we can review fast and reach a determination on fast.

You can request a meeting, you can call us, we'll offer advice, we'll answer questions, we'll even pre-review sections of the documents you plan to submit, like the hazard analysis, say you're on track, you're not on track.

What we won't do is we won't do a complete prior review of the submission, which some people have tried. Innovation and regulation are not incompatible.

Recent innovations we have cleared include self-administered donor health history questionnaires, included via the Internet using audio and video.

Use of biometrics -- so far we've only seen fingerprints. We haven't seen retinal scans to identify donors, the use of digitized tablets to compare -- to capture donor signatures and staff signatures.

We've seen Transfusion Safety Management Systems, which are used for positive patient ID at the bedside.

They may be used when the specimen is collected

for compatibility testing, they aid in the decision to transfuse or not and they may be used to report post-transfusion events.

This last one is something I've seen referred to in the literature as a blood vending machine. The system provides complete tracking of the blood component from the time it leaves the transfusion service to the time it is transfused.

It tracks the time out of refrigeration and warns if the blood component has been out of refrigeration too long.

Maintains a record of the ancillary refrigerators such as the OR or ER, in which the component is located. It maintains a record of the drawer the component is in. What does this mean?

A provider can order a unit of blood or a blood component. The order is sent to the transfusion service by an interface.

The transfusion service software may perform an electronic cross-match. If a compatible unit is in the refrigerator, the transfusion service software sends back to the provider the refrigerator and shelf ID or draw ID in

which the compatible unit is located.

The provider scans the patient's armband and the refrigerator. If the unit is not in that refrigerator, the door won't open.

Now there is an override, say the electricity or something is down. The provider then scans the drawer. If the compatible unit is not in that drawer, the door won't open.

They then scan the unit. If it not the compatible unit in the drawer, the software issues a warning. All of this without human intervention, except for scanning.

Wireless technology which has been a rocky road for all of us here initially, I think we're smoothing it out a little bit.

We've seen that in everything from bedside transfusion management systems, mobile drives, communication between a wireless aphaeresis instrument and its associated software management system.

We've seen something called proprietary dots, which are basically two dimensional barcodes that don't look like a barcode. They're configured by the user,

contain procedural information.

A nurse scans the dot on card or worksheet, for the procedure she wants to perform, in our case transfuse blood, it might be vital signs or other things.

The information is transmitted to the server which prompts the wireless handheld to ask predefined questions and/or give appropriate instructions.

Now, we get to some common misconceptions which I'll hit on, some of the things I've heard, as well as what I've got on the slide.

Probably most common one I hear is all accessories, things interfaced to BECS, require 510(K). Whether to submit a 510(K) is risk based. In other words it depends on the intended use of the accessory. For example, an interface to billing or shipping software does not require 510(K) or inventory software unless it issues used for look back.

Another one is the addition of any interface, even if the manufacturer is cleared for a similar interface, requires a 510(K). The truth is, if a manufacturer has received clearance for an interface of a similar type and protocol, for example, an instrument

interface, they do not have to submit a 510(K) for a new interface to a new instrument.

Interface is also -- let me back up there -- are now reviewed as a special 510(K) with a 30 day turnaround time, which should make many people in this room happy.

Bigger means better -- that's not always the case. We had a large software developer submit a 510(K) that had the following deficiencies, in part, because I only have half-an-hour.

The hazard analysis was not a hazard analysis, but a list of the anomalies that were corrected in this version of the software presented in the hazard analysis format.

There were no software design specifications and the submission had over 300 anomalies or bugs. On inspection of the manufacturer we found significant quality system regulation deficiencies including virtually no requirements or design specification.

This particular vendor did many applications in the -- throughout the country in the non-medical device industry.

Another misconception is that every modification

or enhancement requires a 510(K). FDA requires a new 510(K) for a modification to a cleared device, if the device has a new intended use, new technology, or if the cumulative changes to the device taken as a whole could affect the safety or effectiveness of the device.

This last point is the one that causes most problems. We have same firms who have gone years between submitting a 510(K).

They had gone from version 1.0 to version, you know, 4 or something like this and had not submitted another 510(K) and it hadn't come to our attention, because they said well we didn't have any showstoppers in there.

We in particular didn't add anything that we thought would make us require 510(K), when the truth is they would have pages of modifications which we felt that taken as a whole could have affected the safety or effectiveness of the device.

I do agree with Marsha that the document I want to submit is difficult to read and three people can read it and maybe come to the same or different solutions.

So feel free to call if you're trying to make a decision on that and we'll try to be honest and give you a

honest opinion about what we think you should do.

If you -- let me add some other common misconceptions after hearing the first one. We do use client-server -- most of the applications we have now are client-server.

Many of them are with thin and thick -- I mean, you know, the things that you were talking about. We do have 510(K)s that include recruitment and distribution.

We just don't review that part, because it's not -- we don't consider it clinically significant, but certainly you're going to need that in the operation of your blood center.

So we have many that do that. We have both audio and video right now. It's on the self-administered donor health history questionnaire, which can be silent, they can be touch-screen.

We have paperless donor management systems because they use those digitized tablets to capture the donor signature.

They may or may not use the fingerprint to identify the donor and essentially they have a paperless system.

Hardly anyone that I know of -- and 10 people probably would correct me -- that have self-administered donor history questionnaires, those are usually integrated into the software so that you -- some do but you don't have to sit down and actually input it manually into that -- into the software.

It's actually automatically -- once it's accepted by the employee as accurate and they question the donor with any additional questions, it automatically is stored in your database, so that saves time.

And we have a lot of web-enabled applications. That's also a very common thing we're seeing now, is the majority of them are web-enabled.

So if you have any questions -- that's my contact information, if you don't know it. I included a lot of links and I realized last night of course, that I had not included a link to the guidance on wireless.

If you don't have that you can contact me and I'll be glad to give it you or you can Google it, which is the way we find most things. Just say, you know, guidance to wireless technology and you'll probably find it.

So does anyone have any questions for me? Oh-oh,

first question.

(Laughter)

MR. HARBER: We had to have at least one question, right, because we haven't had one --

MS. WEIR: Yes.

SPEAKER: Could you speak into microphone?

MR. HARBER: So. Well, anybody can --

SPEAKER: And you have to identify yourself.

SPEAKER: I'll do --

(Laughter)

MS. WEIR: Oh, look what I've -- (inaudible).

MR. HARBER: Oh, just being silly. And I forgot my question.

(Laughter)

MR. HARBER: No, wouldn't it be worthwhile to convene like a working group to help define -- you talked about somebody who had done four versions and had been implementing all kinds of changes -- to convene a working group to better define that?

MS. WEIR: That's something we could consider. I think that's a common problem people have. I honestly don't -- I may be naïve, but I think that most vendors are

really trying to do the right thing.

And I always look at things that way when they come in, you know, that it's an honest mistake, and I believe even in the companies that have done that, I don't think they were trying to slip something by. I think they just didn't have an understanding of that. So that might be something we could consider.

MR. HARBER: Yeah, and that seems to be a common theme, so may be some of those other things where people are seeing confusion, I mean, I would certainly volunteer for such a thing.

MS. WEIR: Yeah.

MR. HARBER: People are probably tired of hearing me say that. My last three companies were software companies, so now I'm on the other side.

MS. WEIR: Okay. Molly.

MS. RAY: Yeah, quick question. I want to make sure I understood your slide correctly

SPEAKER: Will you please identify yourself and use the microphone?

MS. RAY: I'm sorry. I'm Molly Ray from SoftwareCPR. On slide 24 it says that interfaces are now

reviewed as a special 510(K) with a 30-day turnaround time. So if the addition of an interface changes the intended use, is -- I just want to make sure that this isn't misunderstood, so that would not be eligible for a special --

MS. WEIR: Well, that's what -- yeah, I know, Molly used to work for FDA years ago.

(Laughter)

MS. WEIR: In those years, that was so chaotic, was it not?

MS. RAY: The painful years, right?

MS. WEIR: Yeah, that was a decision we reconsidered recently and it was also risk-based and trying to be least burdensome and we didn't see any added value to having to see your entire system from soup to nuts, when all you've done is added an interface.

So we may have gone that -- about that in a backwards way, but we decided it was not the intention of a new intend of use, because we really don't need to see all that data and you certainly don't need to submit it.

And I know that your customers frequently want additional interfaces to various instruments and things

like that. And we felt it would be very helpful to the user community to get those turned around faster. So we no longer consider that a new intended use, Molly.

MS. RAY: Wonderful news, thank you.

MS. WEIR: I know, I agree.

MS. SYLVESTER: Hi, Linda, this is Ruth Sylvester with Americas Blood Centers.

MS. WEIR: Hi.

MS. SYLVESTER: You made the comment that you don't look at all the volumes, you only look at the hazard analysis and see them.

MS. WEIR: Well, I wouldn't say that. We do the labeling and we do a lot about this --

MS. SYLVESTER: Well, I understand that and if you listen to this morning's speakers, you know, one of their biggest issues and problem with the whole process is the number of volumes that you have to submit.

Perhaps -- and this would an ideal item to look at to improve and streamline the processes as for the document you really look at. And then if you -- from those you need additional documents, ask those to be sent in.

MS. WEIR: Well, to tell you the truth, we look

at the hazard analysis to try to pick out some critical -- we look at the labeling and I don't -- I don't want to over simplify it. We do look at every single document. We just don't read every page. Oh dear, Jay.

(Laughter)

MS. WEIR: I have a personal emergency. I have to go.

(Laughter)

MS. WEIR: But we do look at all of those documents. I'm saying to get -- it helps us to have that trace -- to be able to go backward and forward and trace between, you know --

MS. SYLVESTER: I understand, but again --

MS. WEIR: And the thing of it is sometimes people on a hazard analysis, when we look at it, they don't have -- they have not identified -- in our opinion, most of us have a medical background -- all of the hazards that should be considered. So if you just --

SPEAKER: And if you --

MS. WEIR: -- submitted the hazard analysis and only those documents that were mitigated in the hazard that -- then you're probably getting a letter any way, because

they are often -- one of things that are often missed in a hazard analysis are what we call implementation hazards that have to do with data corruption, duplicate records, so the -- you know, the hazard analysis is not always perfect.

MS. SYLVESTER: I understand. I understand, and then -- so maybe another thing that could come out of this meeting is how do we improve the hazard analysis that's being done by the industry.

MS. WEIR: Yeah, yeah, I think there's a lot of ways.

MS. SYLVESTER: So that's one thing and then how do we streamline the process.

MS. WEIR: Right.

MS. SYLVESTER: Rather than just having a meeting where we come in here for a day-and-a-half and we, you know, throw up on the slide everything that we don't like about the system, what do we identify to improve, to move forward, is really we're going to try and identify --

MS. WEIR: I think unless Jay tells me I'm crazy, I don't see why we couldn't have something like that that would be useful.

SPEAKER: Did you already cut Jay off --

MS. SYLVESTER: Now step out, Jay --

MS. WEIR: Yeah, I cut Jay off and --

MR. EPSTEIN: Linda, I'm from upper management here to help you.

MS. WEIR: I know.

(Laughter)

MR. EPSTEIN: I think -- and you can correct me if this is wrong -- but I think a way to look at this submission is that whereas we may not read every page, every page is a page we might need to read.

MS. WEIR: Exactly, that's good, yeah.

MR. EPSTEIN: And then I think what Linda is describing is that the pathway into the review is driven by the hazard analysis in the late run --

MS. WEIR: And the traceability.

MR. EPSTEIN: -- but -- and traceability matrix -- but as we do the review, we wander through the entire submission and any given page as the page we might need to look at. If the contact --

MS. WEIR: Well, some people actually look at all pages. We do have reviewers who read every single page. And if it's a difficult review -- I have read every single

page trying to figure out where things are, what they're really doing here, what the problems are.

So I was probably oversimplifying and trying to explain why the traceability matrix was important to us.

MR. EPSTEIN: That's right. With that said, we have an open mind.

MS. WEIR: Yeah, yeah.

MR. EPSTEIN: I mean, if there's a way to streamline submissions, we're all for it.

MS. WEIR: Yeah, I agree.

MS. DAVIS: Rodeina Davis. Since you have an open mind -- I like that Jay.

(Laughter)

MS. DAVIS: I have some confusion little bit in your slide when we talk about enhancement or amendment of 510(K), and I think that is one of the issue that we're really dealing with --

MS. WEIR: Yeah.

MS. DAVIS: -- as a user community with our vendor. If a vendor is going to stay compatible with the technology that they are currently supporting, and I'm going to give an example that can be -- if are on a version

9i with Oracle, and Oracle no longer supporting 9i and they need to go to 10g or something else.

I'm finding that we are having difficulty with our vendor keeping up-to-date with the current technology. Even so they're not any longer supported by the vendor, who -- of the third party vendor, without -- because they have to submit a 510(K), so I do -- and there's an amendment to it.

I do understand the question if you introduce new technology there is some changes. But if you are upgrading your current technology, without other enhancement to the functionality of the system, would that be requiring an amendment to 510(K). I just want to clear up that on.

MS. WEIR: When I said new technology, I was more referring to virus, or you know, something like that. When it comes to operating systems and database management systems, you can -- the vendor can upgrade the operating system to a different version or the database management system without submitting a 510(K).

They just have to test it and validate it and keep that documentation on sides that when John (phonetic) shows up, you know, they'll have that.

Now if you're changing totally, say, from Windows to UNIX, you know, we do want to see a 510(K). Another thing that you might want to consider is that -- and I've just lost my thought. I said if you convert to UNIX -- I've totally lost my answer there so I --

MS. DAVIS: But I think you gave me the answer and I want to make sure that our vendor heard that.

MS. WEIR: Yeah, the vendors, I've found --

(Laughter)

MS. WEIR: That's a common misconception about vendors. Yeah, I have heard complaints from firms. They call me and say, oh, we're having this problem, they want to upgrade and I'll talk to the firm actually and say, you know you can do this without submitting a new 510(K). I think I'm being given the boot here. All you have to do is validate it. Now, if you switch totally, totally platforms then, you know, you do need to submit. Also, I know what I was going to say, just a second.

Also, in the 510(K) if you have -- there are multiple platforms that your software can run on like Oracle and Windows or you know, take your pick, you can submit data for one of those platforms and certify that you

had tested the other platforms to an equal extent, and they were found acceptable.

So they're not limited to just one platform even in their 510(K). So then the vendors here -- okay. If you have any questions, catch me at lunch.

(Applause)

MR. DODDRIDGE: I have a feeling Linda will be getting a lot of questions at lunch. Our next speaker is Tom Walker. He runs a Regulatory Affairs and Quality Audits for the Canadian Blood Services.

Tom has worked in Canadian blood system since 1983, and he's going to describe the health -- Canada regulatory scheme for BECS and that should give us a good comparison between the two models. So Tom, if you'll come forward.

MR. WALKER: Good day. First I'd like to -- on behalf of Canadian Blood Services, thank the organizers for the invitation to contribute to this conference.

It maybe emphasizing the obvious. I'm presenting Health Canada's regulatory scheme from the standpoint of the regulated industry. I'm not the regulator. The regulator is however in the room so --

(Laughter)

MR. WALKER: I mean, if I messed up I'm sure I will hear about it. Well, what do I want to do this morning?

First of all, provide an overview of Canada's blood system, just to put things in context. Then introduce who regulates what in Canada, quickly go over the rules for computerized systems, then look at how the approaches actually work in practice.

I've got three real-life examples and I hope that our suppliers will forgive me for naming them but I don't think I've let slip anything proprietary.

A look over -- I'll talk to the advantages and disadvantages of the Canadian approach and give you the bottom line from our point of view.

Well, this is Canada and this is Canadian Blood Services. Canada stretches for several hundred miles east of Maine to just north of Seattle.

I'm from Point Pelee, which across Lake Erie from Cleveland to the North Pole, and North Pole actually has a Canadian postal code H0-H0-H0.

(Laughter)

MR. WALKER: -- which receives copious amounts of mail every December. Almost over 30 million residents live close to the U.S. border.

Major exceptions are the cities of Edmonton, Saskatoon, and St. John's, Newfoundland. CBS serves nine of the provinces and three territories.

We have 12 manufacturing sites identified thus. They make components. They also include permanent site clinics.

We have three testing labs identified by circles. We have 13 additional fixed collection sites which only collect blood and sent it back to one of the manufacturing sites.

We also have two regional transfusion services. Hema-Quebec, who is also in the room today. Somehow -- I don't know where you are, but I did see you going up in the elevator. Hema-Quebec serves the 10th province, Quebec. They have one manufacturing site and testing site and one fixed site clinic.

The third blood operator in Canada is Cangene. They're a fractionator based in Winnipeg -- old Winnipeg and they collect source plasma for production of

hyperimmune globulins.

A few statistics, and as usual I was working on this presentation very close to the wire, after everybody else had gone home, and the only stats I could find at the time were for the last half of 2006, but the numbers aren't that different now.

We, CBS, serve about 855 healthcare facilities. We have about 4,500 employees and 17,000 volunteers. We have around 450,000 active donors. In a year, we produce about -- or we collect about 870,000 units of whole blood, 50,000 units of aphaeresis plasma almost all of that aphaeresis FFP, although we're trying to build up our collections of source plasma and we also collect about 33,000 aphaeresis platelets.

Hema-Quebec adds about 250,000 to 300,000 units of whole blood, 12,000 to 15,000 units of aphaeresis plasma, and 8,000 to 10,000 aphaeresis platelet units.

Let me introduce our regulator.

(Laughter)

MR. WALKER: Health Canada serves the minister of health. It addresses virtually all aspects of the health of Canadians except the delivery of healthcare and the

practice of medicine which are provincial responsibilities.

The one exception to that is in terms of First Nations and in youth communities. We deal with one branch and within that branch, three directors.

So, yeah, health products and foods brands has a very broad mandate. Most of our staff meet the people from the inspectorate.

They go out and visit the sites every year. But most of our interchange is with the Biologics and Genetic Therapies Directorate in which there is a Center for Biologics Evaluation, so that could give some idea of the translation.

BGTD reviews all of our operational changes, not at devices bureau which is in another directorate, regulates the suppliers of systems used for collection and testing of blood, also computer systems that are considered devices and I'll try and sort out which systems are considered devices in a few minutes.

Now, definitions between Canada and the U.S. are quite similar. A drug is a substance used to diagnose, treat, mitigate or prevent a health problem, or to restore a correct body function.

It's also a disinfectant in Canada. That covers all blood and blood components, stem cells, and bone marrow, so that's why we are regulated.

And the definition of a device is quite similar to what we saw earlier for the U.S. The difference between a device and drug is that a device is a thing or a contrivance, not a substance.

Same sort of uses, few extras included, so blood bags, freezer machines, transmissible disease test kits, the systems used to execute those tests and some computer systems, are all devices.

Now these definitions came from the Canadian Food and Drug Act. The Food and Drug Act applies to the sale of a drug or a device or a therapeutic product and sale does not necessarily mean that money changes hands.

It means that ownership of the product changes hands, so that's equivalent to the U.S. situation. Well, we don't get tied up in concerns about crossing provincial boundaries, so this issue of interstate commerce is not --

A computerized blood system is defined as a system involved in handling data, maintaining or processing data used to determine state of suitability, maintaining

data used to trace.

This is Canadian for BECS. Computerized blood systems are not medical devices. Health Canada is considering revising or removing this bullet about tracing, also making this bullet specific to cases where the data handling involve some sort of manipulation of the data, not just copying a file.

If that change goes through, it will mean that this definition applies exactly to what Health Canada regulates in other areas for other types of drug manufacturing.

They're focusing on the systems that control the manufacturing process. Now these inventory in distribution systems are still regulated.

They're regulated however through inspection. They must employ and comply with GAMP, Good Automated Manufacturing Practices.

A pre-approval submission to make changes is not required, so that makes things quite a bit more bearable. In fact, for CBS, we have not had to make submissions for the inventory system for our plasma products that we distribute or for preparing an electronic packing list for

fractionation of plasma.

One interesting point is that, although this technically would apply to a system used in a transfusion service, it's not currently being enforced because Health Canada does not currently regulate transfusion services.

So the systems -- the version of PROGESA that our transfusion services use is not subject to this. Now when we want to put in a BECS, what do we have to do? Well, we have to provide what we call the seven part submission.

Part one is list the changes to the manufacturing processes and operations. This has to include a description of the software development process and the software development standards which we have to get from the software supplier.

Part two, the plans for validation has to include the overall plans for validating the software including the testing, I believe the supplier is going to do, or did.

Part three, results of the validation plans from part two. So again we need to help provide Health Canada the results of the supplier's testing.

Now, production trial -- okay -- production trail means the implementation of the new system in one location

to contain the damage if the system doesn't work the way we think it's going to. So we do a trial implementation before we roll it out across the country.

So part four of the submission is how are we going to do that. That also has to include plans for dealing with incidents including software bugs and must indicate what support will be provided by the supplier -- full information from the supplier has to be available to Health Canada.

Then we give Health Canada the results of our production trial, our plan for rolling -- finishing rollout to the rest of our sites and a detailed implementation plan.

In contrast, if the system is a medical device, the supplier must obtain certification of their quality system. CMDCAS is a Canadian Medical Devices Conformity Assessment System. So you have to comply with the ISO standards for quality systems. Then you have to submit safety and efficacy data for pre-market review. If you're successful, you will get your device license. You have to bring the registrar in annually for an update and every 3 years you have to go through recertification.

You're still subject to inspections by the -- to visits by the inspectorate. The ISO certificate costs about $10,000 Canadian for the initial certification, 3,000 a year for the next 2 years and about 7,000 for recertification.

Now this approach is similar to that applied in Europe and I believe with Australia. If you plan the inspection and the registration correctly, you can get certifications for several jurisdictions simultaneously.

It's not the same price, it's slightly higher, but it's cheaper than doing it the same way or doing it completely for each jurisdiction. As far as I know however, the ISO certification does not buy you anything with the FDA.

Now, first example, MAK-PROGESA. This is the system we use to control the manufacturing process and maintain our records. It was classed as a computerized blood system. Our first submission to Health Canada on this was in January 2002 and we got our acceptable license amendment letter in October of 2005.

Now, most of that 55-month elapsed time was

related to the rollout of the 14 sites -- 14 at the time, and resolution of some issues around our contingency plan for what we were going to do if the system crashed.

There we are. Now, BGTD, we understand requested considerable information from MAK and essentially it was the information that Linda Weir just listed with the 510(K) submission and it went to Paris for an onsite data review. BGTD focused the review on the changes that had taken place in the MAK system since they received their 510(K) from the FDA. So the 510(K) actually gave MAK some advance standing.

Also our review was expedited somewhat by the fact that Hema-Quebec had had their MAK implementation approved ahead of us.

Then we decided to upgrade our laboratory information system and we chose HSS Surround (phonetic). We use it to consolidate all our testing results and upload it -- upload them into PROGESA.

We don't maintain any records beyond 30 days. This system was classed as a medical device because it looks at multiple test results and determines the final interpretation and a medical lab or a hospital could afford

to buy the system and use it for similar purposes.

Now, we submitted that in October 2005, got our permission to proceed with implementation in December 2006.

We're still finishing the submission on that. We owe Health Canada information on disaster recovery process.

Now, we had to provide a description of the software and development standards from the supplier to both Medical Devices Bureau and to BGTD.

Part of this was because the system was not -- is not a licensed device. We are importing it under what are known as special access provisions.

There are no licensed systems like Surround in Canada, although many medical labs have installed OIS. May be they are not using them to interpret data, I don’t know. If it had been classified as a BECS, we would only have had to deal with BGTD.

Final example is HSS (inaudible) system. We are proposing to use this to implement electronic health screening. It's been classified as computerized blood system. And I have the question mark there because I still don’t fully understand why, but I'm not asking the question because I got the answer I wanted.

(Laughter)

MR. WALKER: We don't have any idea of the time to review. I believe the -- it wasn't called a device because the system only consolidates information.

It doesn't interpret -- does any interpretation -- the interpretation is made by the screener. But it doesn't align with the definition of a computerized blood system either, because it makes no decisions and it doesn't store data, so.

The requirement information that Health Canada require -- regardless of what we classify it as is -- it lines up with the outline of the seven-part submission anyway, so we're just proceeding with this and trying to get through as quickly as possible.

So, what are the disadvantages of this approach? One, we're the intermediary between the supplier and Health Canada. So we have more workload, more responsibility. We have to enforce quality system requirements and we don't have any guarantee that the supplier is going to tell us about problems that an ordinary customer has detected.

We have more to submit. The division between BECS and other software is very confusing, difficult to

understand, and the requirements are inconsistent between BGT and medical devices.

On the other hand, we don't have any problem of finding suppliers. We can go shopping for any BECS available anywhere in the world. And certainly we've got evidence that the medical device licensing is impeding the availability of lab information systems based on our experience with Surround.

We only have to deal with one regulatory body and that happens to be the one that's most familiar with what we do. Bottom line is we think the advantages -- the disadvantages and not only should BECS continue not to be regulated as medical devices but computer systems should not be regulated as a device unless they are sold to healthcare providers. In other words, they are actually used directly in diagnosis, treatment, medication, et cetera.

So, once again I'll thank the organizers and thank you for your attention. Mr. Chairman, I return the floor to you hopefully in good condition, and if there's time for questions, I'd be happy to try to answer them.

(Applause)

MR. DODDRIDGE: Okay, can you hear me in the back?

SPEAKER: No, turn it up.

MR. DODDRIDGE: No? Okay can you hear me in the back?

SPEAKER: Now.

MR. DODDRIDGE: Okay, if there's no questions for Tom -- I'm sure he will be available throughout the day if you do have questions.

This time I'd like to bring forth a good friend of mine. I've known him for many years and I can tell you one thing. If you are in Scotland, do not let him take you out for a scotch tasting.

(Laughter)

MR. DODDRIDGE: You will regret it the next morning.

Angus Macmillan is from Scotland. He's the former head of the Scottish Blood Transfusion Service, and is now a consultant and it says on here a small farmer. I'll call him a gentleman farmer. He is not small. And he's going to provide us with an another model for comparison sakes, the European regulation of BECS.

Angus.

MR. DOUGLAS: Thank you.

Don, thanks very much. While this is being set up, I might just tell you it's always a great pleasure to come to this country.

I arrived at your board of controls last evening off a British Airways flight and a pretty chatty and delightful gentleman said "I see your name is Angus" and I said "Yes" and he said "Like Aberdeen Angus cows."

(Laughter)

MR. DOUGLAS: I said, "You've got the name right."

(Laughter)

MR. DOUGLAS: And he said what are you going to do here, and I said, I'm going to a Health Conference, and he said, "Well, I suppose you're going to be speaking on mad cow disease."

(Laughter)

MR. DOUGLAS: So you have very pretty intelligent border guards, I think.

(Laughter)

MR. DOUGLAS: Right, this -- the purpose of this

slide really is to emphasize two points. Firstly, that -- I am by no means an IT expert, what you will be getting here is a management perspective, a management overview, if you like.

And secondly, the information contained in this presentation comes from some work that Martin Gorham and I did with ABO members, the Alliance of Blood Operator members, around Europe and North America over the last 2 years to get the impressions from blood services, from one regulator, and from pharmaceutical companies on the best way to regulate IT.

I'm actually only going to touch on Europe, a certain amount, a little bit at the end. This is actually a Transatlantic set of information.

The objective of the -- objectives of the session, to really, I hope justify a considered judgment amongst the blood transfusion services that we've talked to. The lack of choice of IT systems, which presently exists in much of the developed world, creates a major strategic risk.

And that is not to criticize the providers of systems that do exist, but it is to say that that is a

limited choice.

Secondly, to try and justify that blood transfusion services in Europe and the United States are doing what they can to reduce that risk.

Thirdly, to try and justify that the risk cannot be adequately managed without some help from the FDA, and fourthly to describe the position in Europe, which is by no means perfect. I'm not going to suggest that but the regulatory position is slightly different.

So what IT systems are we talking about? What are the risks? Why can't blood transfusion services and IT providers manage these on their own?

Well, blood transfusion services as everyone in this room knows, but not everybody knows, are dependent upon the IT systems for maintaining quality, safety and management decision making and control.

We are all dependant on IT systems. I will give examples of this, but in summary, I would just make the point that once a blood service moves to a fully integrated IT system, there is no safe way of going back even for a day.

The IT system must work 24 hours a day, 365 days

of the year. Therefore, if there is a failure of the IT system or a lack of capacity of that system or linked systems there is a real strategic risk to the provision of safe and adequate blood supply to the area that the blood service covers.

And this is why the Alliance of Blood Operators has classified this particular risk as one of its globally strategic issues. And it only has, I think, around 4 or 5.

And that surely is why this meeting today is so important. It's basically saying that the status quo across the developed world isn't safe or isn't sufficiently safe.

So what do IT systems actually cover and Rodeina Davis did a much better job than I'm going to all of this. She -- but I will still go through these things again, because it really does demonstrate just how much we are dependant upon IT systems.

(Tape interruption) -- relationship manage issue at the front end of our services, the donor relations. The strong support logistics from the donor sites back to the processing and testing sites and then from the processing and testing sites out to the hospitals.

There is what I've called the core systems, the blood testing and processing systems. The process control linked to SOPs which are at the heart of all of our organizations and which the BECS systems really address.

The stock management, which may or may not include hospital stocks -- in Scotland where I've managed the blood service for a few years, we moved to include most of the hospital stocks.

In other services it doesn't necessarily do so. But the link to hospital systems is absolutely critical, because without that you can't ensure traceability, and nor can you reconcile the amount of blood you've given the hospital with the patient records. You actually don't know how much blood is being used, except on a subtraction of the amount of blood given and subtracting the amount of blood given back, which isn't perfect.

Demand forecasting -- a area that many services are now getting more and more involved in, because you can actually, in many of our services, forecast demand.

You may not be able to forecast it perfectly but you can certainly forecast it within confidence limits. And then there are all the support services IT systems

which are so important to the management, and interlinked anyway with the operational ones, the HR ones, the payroll -- the payroll and finance and costing systems. And the individual pieces of equipment, the medical devices which have their own IT systems as part of them as -- if you like, closed systems.

If these are in place, if all these things are in place, and are linked, they facilitate management's ability to manage safety and effective operations. Any break in at least the top or five of those bullet points creates a safety problem, I would suggest. And therefore the message from this slide, I suppose, is that IT is fundamental to safety in the modern blood transfusion service.

So what are the risks, what actually is the problem? Well, first let's look at the background. The global blood transfusion service market is relatively small and is highly fragmented. In many of the services, there aren't very strong IT teams. Clearly, there have been some exceptions to that that demonstrated today. But many services except in Europe don't have very strong IT teams. And the IT providers themselves, as you've seen, the

providers of the core systems are relatively small. Therefore there are certain risks which certainly were perceived by drug services and others when we went around and talked with them.

In-house systems are becoming increasingly fragile; it's more and more difficult to actually keep up -- keep your in-house system up with latest technology, et cetera. Limited choice of commercial off-the-shelf systems, so-called COTS, I've already mentioned. The capacity of the COTS providers -- this is a risk; the customer support, their ability to retain their staff, their ability to keep up with new technologies, their ability to link to other IT systems, and their potential financial and organizational strength; in other words, the sustainability of the whole company.

Now, many of these services do a first class job, and I'm certainly not here to criticize them. I know what the blood transfusion services that we talked to. But these risks just are the risks of relatively small companies trying to be at the cutting edge of their particular business. Also if you're going to run any organization effectively, the overall management

information system; in other words, all these systems we saw before linked together is what really provides you with the best service.

And that is what the pharmaceutical companies we talked to said was the big advantage of going to generic providers. Yes, there was a high cost of getting there, but they, if you like, contracted out the risk and they got linked systems.

So if we look at these strategic risks from a slightly different perspective, from a very head-on perspective of the blood service, there is the risk of a service going -- of a provider going out of business, through financial failure or some other reason, the failure of the in-house system to be able to keep up with best technology, or to continue to maintain the right level of staff.

There is always the risk of a small provider being unresponsive, especially in the event of operational systems failure, which is absolutely critical if the service -- if your service is going to continue to provide the blood that it should do in a safer way, as it should do.

And it is difficult to link the COTS provider system to other management systems. Now, this doesn't -- wouldn't matter in many markets. We, every day, make judgments about whether we're going to go for very large companies to provide us with services or smaller perhaps more easy to deal with companies. We make these judgments every day, both traditionally -- both professionally and personally. But normally, you would have considerable choice in the market, and if you have choice in the market, you can exercise what sort of provider you're going to.

What I hope that I have demonstrated is that there are a number of blood services, certainly in Europe, and I know also some in the U.S., who are concerned about the lack of choice of commercial off-the-shelf providers. And they consider this does create a strategic risk to their business, and therefore of course to their customers.

Now, I was certainly impressed going around the blood services; how much they are trying to do to manage this risk yourselves. Many services are adopting a modular approach to system selection. You have a personal

system, you have a donor system, and you link these together.

Now, obviously, that reduces the systematic risk of failure, but it does have the disadvantage that you don't have necessarily a comprehensive management information system. Many services are limiting the customization of their computer services as much as possible to reduce the complexity of support and the time required to problem solve by a vendor. And this obviously also is an extremely important way of reducing the risk because you don't have a different system effectively in every center, but some customization is almost inevitable.

Services are trying to ensure that they have what we call certainly in the U.K., super users; people who are not IT experts, but understand the system so well that they can keep it up and running if there is a small failure, or they can do basic work-arounds in case the response from that provider is not as quick as they would like. A number of services are negotiating source code escrow agreements with the COTS vendors. So if the vendor goes out of business altogether, they can actually get to the basic ingredients of the "black box," if I can put it

like that. And so potentially, they can keep the system going. But I don't know if one of those things has ever worked in practice, and there really is potentially a risk if a provider goes out of business altogether.

And many services are working closely with their providers to identify and reduce risks wherever it is possible to do so, and try and put support systems in place wherever it is possible to do so. So we certainly found the blood transfusion services are acting themselves to try and reduce the IT risk to their businesses, and to the product safety. But none of these measures deals with the risk of having limited choice in the market.

Now, as the alliance of blood operators, we have discussed about how you might increase choice in the market, one or two blood services could try and achieve greater choice by encouraging a generic software provider to enter the market. But we've got to face here the market realities. Blood transfusion service market for IT systems is relatively small, it is highly fragmented. The United States makes up about 30 percent of the developed world market; Europe makes up about 50 to 60 percent.

So it's very difficult if one large component of

this market is not, for one reason or another, welcomed by the generic providers to increase the number of providers who might enter the market. And this does bring back the focus on to whether -- regulation could be based more on whether systems work than in practice and in operations than before -- than go through a whole licensing system before they are marketed.

But of course, this is very difficult because there are different legal systems and different traditions. Pharmaceutical companies -- and I talked to two -- normally do use the generic systems. They recognize there is considerable investment upfront, but they do effectively transfer the risk to the IT provider.

And I suppose in a sense that would also transfer some risk from the regulator to the IT provider. But it does take an upfront investment, and it does mean that once you've got the system in place, you've got to follow it, and not have lots of local customized sort of subsets of it. Also, if this was going to happen in the blood transfusion service business, it would require a coordinated approach within obviously competition rules to attract and maintain long-term commitment of the generic

provider.

So some suggestions for discussion; blood transfusion services themselves can reduce the risk of a lack of choice in information system providers in a number of ways. We can move away from a cottage industry approach, we can move away from wanting to tailor individual systems at different sites and even between certain different services. And we can try and have a management discipline that makes it easier to manage the system from a center, and therefore to repair things that go wrong.

It is possible that blood services are unwittingly contributing to creating a small and high-cost market for vendors to penetrate; also incidentally, a market with high reputational risk. So it is important the market is made attractive to vendors because if they do fail, not only is the financial risk high, but the reputational risk is extremely high as well. But there are some causes that certainly we found the blood services cannot overcome on their own. The size of the market outside the U.S. is probably -- at least in the developed world, is not sufficient to attract the generic vendors,

and that very much throws into the spotlight, the importance of the regulatory regime within the U.S.

If we can't resolve this issue, then we're left with these perceived risks. Now, let me go on a little bit to Europe and where Europe differs slightly from the U.S. Firstly, each European country has its own regulators -- got a big difference in itself. But the general differences from the -- between Europe and the U.S. are the next three bullets.

In all European countries, it is the responsibility of the commercial off-the-shelf provider and the blood transfusion service to design and implement an adequate IT system. And that includes local tailoring; any local tailoring that might take place in order to maintain safety and protect the patient.

That has implications of course, because it means the legal liability stops with those two parties. And of course, the fact that many blood services in Europe are owned by national governments may make that easier to manage than if they weren't. The regulator is not normally involved before the IT system is designed, marketed, and implemented within the BTS. This clearly

may be different for closed systems within a particular device, but the logic on why the regulator isn't involved is because the -- certainly, the U.K. and German regulators work on the basis there will be some local tailoring and they would rather inspect it when the system was in place, rather than in its generic form.

Then of course, the regulator inspects the blood services IT systems as part of its general operations to ensure that the blood services outcomes meet requirements. Now, I think the service that I am slightly surprised has this open approach as this, in a way is the German one, which I know reasonably well because in Germany, blood products -- product components are licensed.

And the normal approach -- which they are not in most other European countries -- and therefore the approach in Germany for a device is normally that you have to get the regulator's approval before the device is implemented, and then the state, the "lander" within the country inspects its actual operations to make sure it works as expected or as described. Now, the reason that BECS systems are not included in that process is because there is an assumption there would be some tailoring of

the software after or during implementation. So I don't know if that logic is -- transfers in any way, but that is the situation as I understand it in Germany. Ladies and gentlemen, thank you very much.

(Applause)

MR. DODDRIDGE: Do we have any questions for Angus before the break? Okay, thank you. Just a couple of housekeeping -- the proceedings are being recorded and there will be transcripts made available by FDA after the conference. And also, I remind you to pick up your breakout slips that -- which session you're going to this afternoon, I think they are in the back of the foyer, and lunch will be in the Chesapeake Ballroom, and I believe that's to the left, and Marie (phonetic) and a couple of others will be back there to help you on your way. And we will try to reconvene at 12:50. So keep that in mind, 12:50 is the time to reconvene. Thank you.

(Whereupon, at 11:57 a.m., a luncheon recess was taken.)

A F T E R N O O N S E S S I O N

(12:51 p.m.)

MR. DODDRIDGE: Okay, I would like to go ahead and get started. I'd like to introduce our next BECS speaker is Joan Loreng, who performs inspections for the FDA focusing on biological IVDs, pharmaceuticals, vaccines, blood banks, and most relevantly, blood banking software. And I can attest for that she's done our inspection a couple of times on our software. Joan is going to give us some insight into FDA's field experience, including BECS manufacturers and blood establishment. Please welcome Joan.

(Applause)

MR. DODDRIDGE: And while Joan is coming out, I do want to make one announcement. People have asked if they could submit written questions. If you all submit those to Bob, we will find time.

Bob, hold up your hand again, and get those questions to Bob, he wants to make sure he can read them. And we'll find some time before the end of this session to see if we can have those questions answered.

MS. LORENG: Thank you, good afternoon. So the objective of this talk is to provide a basis for the understanding of the inspectional process for blood establishments and for software, blood software vendors. And I'm sure some of you have run in -- run across me, or I've run across you in my experience.

SPEAKER: We can't hear you.

MS. LORENG: Okay, I'll try again. I'm going to -- it's not on?

SPEAKER: Well, checking.

SPEAKER: It's a little red line on it.

SPEAKER: Well, it's just gone off. Let's do this.

MS. LORENG: And can you hear me now?

SPEAKERS: Yes.

MS. LORENG: Okay. Okay, the objective of this presentation is to provide a basis for the understanding of the inspectional process for the blood establishments' software vendors and for blood establishments themselves, and to discuss the regulations applicable to each of those.

So what I'm going to talk about is inspections

and the inspectional process and our authority to do the inspections. I'm going to touch on validation a bit, and the difference of the degree of validation is actually possible at a user facility, which is different.

And some comparisons I was asked to talk about was -- I wasn't personally asked to talk about, but nobody else came up to the plate --

(Laughter)

MS. LORENG: -- was drug inspections and drug manufacturing software versus blood establishment software, and my feeling is they are very different. And I will talk -- so I'll talk a little bit about that.

So inspectional blood establishment software manufacturers, we inspect for compliance with the quality system regulation that's 21 CFR Part 820 that would -- and also with the medical device reporting regulation, and with the correction and removal regulation. And the QSR are basically the GMPs for manufacture of a medical device. And the MDRs require that any incidence of serious -- death or serious injury be reported to FDA whether or not it's a malfunction, and then if it is a malfunction, even if it didn't cause a serious injury or

death because it has the potential to, that needs to be reported also as an MDR.

Then corrections and removals are really just another way of saying recalls. There -- in the past, there have been what we used to call in FDA, "the silent recalls." Or somebody would send out a field correction or something like that, and not notify the agency that they had in fact recalled this product; "We've done a field upgrade," or something like that.

So the quality system regulation, according to our compliance program that we use to inspect medical devices, they're divided into 4 major subsystems; management controls, design controls, and production and process controls; and corrective and preventive actions.

Now management controls, it's more or less -- this requirement here that I didn't list, it's that the management should have a quality policy. So it's giving the overall -- well I'll use the word "philosophy," but I have to tell you, we had one training --- web training that I was asked to review, and it actually said that when we go into a firm, we should determine the firm's philosophy.

And I said, "Well, wait a minute; we don't inspect philosophy, we don't regulate philosophy, I wish I could, but okay." So you know, but it didn't -- I can think it kind of meant the policy, like do you have a good quality policy, and will you take responsibility for it and stay informed of what's going on.

So they need to assign responsibilities for different activities, provide adequate resources -- and that's a very big issue -- the resources, maintain oversight, and that's usually by these meetings, and they have them periodically, usually big manufacturers -- I mean, at least quarterly -- where they look at the complaints, the time to resolve a complaint, any issues, are they -- are the projects on time and things like that. And so they need -- and we need to review the suitability and effectiveness of the quality system.

Design controls: In my mind, the design controls in the QSR are closely aligned with software development lifecycle principles. You know, you have a requirement, the requirement becomes a specification, it's an iterative process, you do a risk analysis, you have control over changes, and not only -- and have SOPs for all of the

activities throughout the lifecycle of a software.

Okay, I've left out verification and validation -- I said that -- and of course documentation. We always need to see documentation of any activities performed. Now, production process controls: People might argue with me about this like, where does it end for software because except for the media, you really don't have a something, you don't have an object.

So what I tend to think of it is, is that configuration management where you're putting together those different bills and rolling them up into a release. I think of that. Of course, the QSR, you might think of that as design transfer. So and that's under the design control part. But I like to think of this because when there are changes made, you have to go back and make sure that the most up-to-date version that is to be put in a certain release is rolled up and compiled.

So version control, release notes, creation of those in the user manual, but specifically the software duplication, distribution, and installation. Now in device regs, installation can be done by a third party or something like that, but a lot of vendors actually install

electronically, the latest software into the testing and validation environment.

And in the release notes, we would expect to see any -- I've seen, I've been to blood establishments, and I've seen good and not so good release notes from the vendor. I mean, you'd really like to see is it a mandatory upgrade, is it a cumulative upgrade, so they know if it's not cumulative they need to install all those previous versions.

Be upfront about the bugs that have been fixed and put them in the language that the person can understand. You know, yeah, it's nice to promote your new features, but you know, if you could say these bugs have been fixed, you know, it's really -- it really helps the user and they can, you know, to have more control and more confidence in what they're buying.

And corrective and preventive actions; again in blood establishments -- oh, I'm talking about devices, I shouldn't talk about that. Blood establishments now are using this word "CAPA," even though it's a device reg. Okay, and back to the device.

The QSR says you have to identify the defects in

the product and they should be externally identified from like the help desk or the user complaints; things like that, but also be internally identified. And sometimes, there's two systems I don't see integrated. I see the -- and I don't mean just electronically.

Electronically, there are systems built for each of these functions to track bugs on the software side, and then to track complaints where the SMEs help the people through the problems.

But at some point they should be integrated, so that if a complaint comes in, you can relate that complaint number to this bug, so that you have traceability and see that, you know, all the complaints are being addressed by a certain bug and then the bug fixed. And they should hopefully identify at what phase that bug was identified; was it during testing, during the investigation of another defect, or during development of a software update.

A manufacturer of software needs to identify the defects in the process. This is another thing that we see lacking a lot of times, they'll fix the specific requirement or the specific specification -- they'll fix

the specifics and they don’t look globally like, could you improve that requirement definition phase, or you put it, so the requirement is more understandable, so when the person links it up to the spec to implement that requirement, it's clearly understood.

So there's a problem then with the communicating requirements, the subject matter expert communicating that to the programmer. And we do see problems here that the programmer assumes something, you know, and then the SME assumes something and they don't, you know, they're at cross-purposes, and -- well, I said is translating the requirements into specifications, adhere to programming standards, did the programmer not adhere to your defined programming standards.

They need to make the peer review more rigorous, develop better test cases, so that you will catch those types of errors in the future, and is the testing rigorous enough. So this is like, look at the process, not just the discrete issue in CAPA. And you should have a deeper tracking system so that the problems are -- that are identified, that they're captured in some systems, so you know, you get it done -- but a lot of people we see, they

want to decide what it is before they capture it, and sometimes it gets lost because it's not captured as soon as something happens. So you know, capture the event and then decide what it is.

Okay, talked about this. Oh, so the corrective of action could be correcting the code, it could be developing work around -- it could be just notifying the users that they're aware of the issue. It could be to correct the requirements and specification documents or correct the test plan.

Examples of preventive action on addressing the underlying cause of the deficiency is better definition requirements, better communication between the programmers and subject matter experts, keep them in the loop throughout whether, you know, as the project is going on that they're in communication, an understanding if things change, or the SME wants something done, but it's very difficult, you know, compromise that maybe they can't have that nice feature they want to have; they have to compromise.

Enforce programming standards and develop a knowledge base. A lot of places I've been to have what

they called a knowledge base, where their program is like, if they see people are tending to forget things they should be doing, the standard operating factors, but they are not doing it, they haven't -- they put it up in a knowledge base, you know, that they can go to see if there's a similar problem there they're coming across now.

Okay, medical device reporting which we inspect for adherence to the reporting requirements, which I said, a death or serious injury caused by your device or a malfunction that may cause a death or serious injury.

Problems we've seen with the programmers and the software developers are on understanding the requirements. This misunderstanding, we've seen it in -- mostly, I've seen it when changes are made. I've seen it like when somebody makes a change to defaults, and the ones that always get them are the two-time hit for CORE (phonetic), and the two-time hit for HTLV. The programmer doesn't -- sometimes doesn't understand that that's different from all the other defaults. So they're making a change here and then not realizing that, oh, this was actually in one place called another variable in another table, and they totally didn't see it anymore because they weren't looking

for that variable.

And explain the limitations to the users, so they understand that, you know, I think it's where the -- Sheryl and Linda both said that the user sometimes thinks the software can do everything, you know, and it's like things have to be done in a certain order; you get out of that order, you got to make sure this that, you know, the software goes back and reiterates, you know, that that step that you interjected there or overlooked.

Now especially, you do something like change a default; if you have to go in and change that or all the other processes, or change a test result is they're going to go back and look, and upgrade the default.

So okay, inspection of blood establishments; all the blood banks are saying they know this really well. Compliance with 606s, 640s and the 211s, the quality assurance issues and the 211s and the software -- software at a user establishment is regulated under 21168, for intermediate equipment. Those regs are old; we're trying to update them, but we're not there yet. We keep getting comments and getting turned back.

But I mean we do -- we do try to address your

issues with the regs. But we got lawyers and they don't --

(Laughter)

MS. LORENG: I mean, why are we asking you do this, like we even had one about like why do you want you to write a report, it's like how the heck do we know what you did, and how do you know what you did if you don't like summarizing a report.

But, that's the kind of things we get, and then we -- you know, then it goes out, then we get comments from other people that have things they don't like done. Okay, and then for biologics and blood stems, we have to -- it's quite analogous to MDRs -- but the BPDRs, the Biological Product Deviation Reporting.

So for blood establishments, we go by compliance program, 7342001 or 002 for source plasma establishments. And right now, to conserve resources, we -- I don't think we are using these words because people think "Oh, gosh, if you don't abbreviate it, you are not doing as good a job. But I mean, it's basically what we used to call a comprehensive inspection or an abbreviated inspection. We are doing -- but we got in there, so people wouldn't

overlook the biggest thing, the worst thing could happen if blood establishments should release an unsuitable unit, and you're all aware of that.

So during all inspections, we put in there that the investigator has to check that to trace reactive test results to the unit, to the default, and just make sure taking a sampling of reactive units that shouldn't go out, that they do not get out the door, because initially when the program was devised with this comprehensive abbreviated testing was considered a system, and so nobody can just take testing out, I mean.

So we had to make sure that, you know -- I mean, to me that's -- well, that's the biggest part of our job, you know, to ensure public health and that reactive units aren't released.

So -- oh, and then another thing that's a misconception too; inspections. Well, we've had investigators and when we got criticized by GAO many years ago, GAO -- Government Accountability Office and the -- whatever the other heavy ones, yeah, criticized by some other people too.

(Laughter)

MS. LORENG: Now, we weren't looking at the computer systems, and I said, don't ever put that in the report you don't look at the computers -- you're looking at electronic records all the time. You're looking at inputs and outputs. So don't say you don't look at the computer system. I mean, maybe you didn't look at the validation of it or something like that, but you're always looking at data entry transmission and reports coming out of that computer.

So okay, but if you are specifically looking at computer systems, we want to look at the documentation of the system components that you have defined your system, and know what it is. But you have to define certainly before you validate that. It is really obvious, but you'd be surprised that people think they can jump into validation without defining what they're validating. Have to do equipment qualification; document their user-defined tables, those things like what kind of default codes are you using, what kinds of dating, for what kind of products and those codes.

User acceptance testing and validation, change control; that you have change controls and you know when

you put a version into use in the production environment, patches and take those user-defined tables if you've changed them, so it's traceable when that happened. You need to document those errors.

Again, in the past it used to be something -- a computer error was like sacrosanct, and nobody documented it like you're documenting every other mistake people are making. But if the computer did something funky, you didn't you didn't document it. So we want to do that.

Security; especially, you know, in this type of -- in the blood industry, the security is very important. You know, the access privileges, who can go in there and enter data, the personal registers, how much can they see and is their security access commensurate with their job description and what they're expected to do. And of course, we'd expect that for the person that could go in and change your test result or change a default that they will have higher security privileges. And there should be a process for that, not loosey-goosey, like you have a SOP for how you're going to assign security access and things like that.

Okay. Problems we've seen at the -- the user is

also understanding the limitations because what's obvious to a blood banker isn't always obvious to a programmer, and vice-versa, and with an IT person. And performing operations out of the usual sequence; it's hopefully, your system can recover and go back and do the operations that have to be done to make all the related things happen.

But we see that as a problem. And I don't put in here, but I should have put -- another problem we've seen is for the big establishments and you know who you are.

(Laughter)

MS. LORENG: Sometimes, the systems have been done for the features and not the performance capability, and can it really meet your needs for the number of concurrent users, the response time, processing time and things like that. So that's an important, really important consideration, can it meet your workload.

Okay, validation. Because I've heard said that, you know, the users can validate it, and why do we need a vendor -- why do we need to regulate the vendor to make sure they're doing a proper validation. Well, the manufacturer knows the design, they know the source code.

They can put forward a detailed risk analysis because they know the risk mitigation strategies they used.

They can do white box testing. They know if the programming standards and design rules were followed, and they can challenge the design, the file structure, the relationships, and the application software. The blood establishment doesn't know the design, they don't know the code, and even if they had that thing, will they go out of business and with the --

SPEAKER: S curve?

MS. LORENG: S curve, thank you. You know, they -- that's future if they're -- well, I have seen that code transferred to people and people have taken it up and, you know, worked with it. But they don't know the designer code. They can only perform a really -- in reality, a high-level risk assessment. They can identify the critical functionality on what they've done to mitigate, but they don't know what's going on behind the scenes in that code.

They can do black box testing. They can -- after they've identified these critical activities, they can test that the user defined tables they have created

work properly, and things like that. They can evaluate whether programming standards or design rules were followed; maybe they do inspect that vendor, but maybe they're not allowed into that vendor, I don't know.

But even if they were, it's just like us. We don't see everything when we go in. You know, we're like taking a snap shot, and so -- and they can't challenge the designs, since they don't know how it was designed. And that's proprietary, and I don't think they're going to be told that.

Okay, so the validation of blood establishment; they can execute the manufacturer-recommended test scripts, and I don't see anything wrong with that. I think most of those vendors know the -- like I said, they know what's -- how it's designed. So they know how best to challenge it with the user-defined tables, you know, for that user. They give recommendations of how to define those tables. Then they execute their own test cases, they qualify their equipment, they verify that the networking is working, and they verify the performance of their maximum workload.

And I just want to point out that there is a

draft guidance on validation that went out that the blood bankers, I'm sure, have seen, because it is for the user establishment. It was issued in October, we got comments; we looked at them, we didn't get any really bad comment, and so any clarifications are going to be addressed. So they had to go back to the lawyer, so we'll see when that comes out again.

So -- oh, and then, I was -- like I said, I was asked to talk, by default, about drug establishments. And I have inspected drug establishments; I've done it recently, so this is what I see. There's automated -- in drug manufacturing, there's automated equipment; there's programmable logic controllers that the manufacturer puts their recipe into, okay.

Then there's a distributor control systems, there's supervisory control and data acquisition systems, there's LIM systems for the laboratory testing, there's the MRP, which is material resource planning which is two steps down from the ERP that was mentioned -- enterprise resource planning. And the MRP is basically an inventory management system in the drug facilities.

So the comparisons; you really needed to define

the functionality before you start making a comparison. You really need to define what you're taking about. So let's do a little of that. Okay, what's the raw material in a drug facility?

It's a material, it's a substance. They have approved supplier list, and it's either yes or no; it's an approved supplier or not an approved supplier. They have incoming inspection and/or testing, and that's either pass or fail. One lot of a raw material drug can be used in multiple finished product batches.

Now for blood, you have the donor history. The donor comes in off the street, and there's the questionnaires, the medical history is taken, the testing is done. There's algorithms to determine acceptability considering all prior donations and the medical history. Testing those algorithms to determine the acceptability of current donation and future suitability -- and it's one unit; one donor, one unit; multiple components, but basically one unit. The testing in drug, there's multiple testing of this during drug processing.

There's multiple in-process tests performed, there's finished product testing, and this is even when

they're using process analytical technology that's kind of like in-line testing, but it's still -- it's multiple testing event. You have multiple occasions where you can catch if something is going wrong whereas in blood, there's one test of record for the ABO, and there's one test of record for each trio marker. So I consider them very different.

Comparisons: drug problems with the system in my mind may be more easily detected; you have automated equipment, there are sensors, there's alarms, there's printouts, there's feedback groups, there's just -- in distributor control system again, it's another level above the PLC piece of equipment. There's monitoring and alarms and printouts, you've the in-process testing again, you have finished product testing, you have hardware and software controls.

And expiration dating is another example. In drugs sets assigned from the date of manufacture; whatever they consider the date of manufacture, which may be the date of filling or some date, but it's a set date, and then it's 24 months or 36 months from that date.

In blood, the suitability of product for release

is dependant primarily on software algorithms. It's software. The suitability of product for transfusion to a patient; you take the history of the antibodies, warnings of being compatibilities are generated again by an algorithm in the software and computerized cross match.

Again, all algorithm-driven, not discrete testing, and yes or no into the inventory management system. Expiration dating, again in blood, I mean it's calculated initially from the component that is manufactured, but then it's modified.

And then that modification can, you know, when they started irradiating blood, they had one product and then, you know, there is an algorithm to determine that it's, you know, would never go beyond its original expiration date, and be confined by the new expiration date.

So in conclusion, I discussed -- and the market and size, I'm not going to run through this, even though -- discussed inspection of drugs manufacturers and blood establishments. I touched on the validation by the developer versus validation by the user, and I identified some differences in processing of drug products and blood

products.

Oh, I do want to say one thing when, you know, another issue was made about -- I hope I got this right, I wanted to ask you a question, but I didn't get up in time -- about the Canadian paradigm. And so it's not called a device, but the regulatory authorities can go into that facility at any time. See we are constrained by our law, where if it's not defined as a device, I don't have any right to go in there.

I mean, I need -- it needs to be something that we regulate for me to go in there and give a notice of inspection and poke around. So, if I got that wrong, let me know. But I mean, that's -- and in Europe, where you know, where it's mentioned that they were regulatory. The blood systems were owned by the national regulatory authorities, well that's a lot different too. They can go in there at any time. So I just -- I just thought that should be, you know, highlighted that -- you know, if it's not a device, we don't have any right to go in there. I mean, in cases of emergencies, I've had to go in places, because like a PCB leakage or something -- and I was asked to go out. Well, it was like, "What are you doing here,

you don't regulate us." And I'm like, I'm trying to do you a favor, you know. You don't have to let me in, but I'd like to give you some information that could be beneficial to you. So that's all I have.

(Applause)

Thank you.

MR. DODDRIDGE: Thank you Joan. Are there any questions for Joan?

SPEAKER: (Off mike).

MR. DODDRIDGE: Yes, please.

SPEAKER: Looking at the design controls and production process control slides that would be on page 3 of the handout, and this is -- question is not necessarily directed to you, but looks at the people who've gone through this process before. What would be your opinion on how well defined these design control and production process controls are under the FDA regulations? If you could (off mike) --

SPEAKER: For drugs?

SPEAKER: -- and people who have experienced it, how well they define.

SPEAKER: Are you asking about the actual

regulation?

SPEAKER: The slides here say that design controls are not software development principles, and software development principles come in as many colors as there are stars in the sky. And you can pick your choices on what it makes it good or bad software designing development method, and there are many of those.

How well would that define as people run through the process, how well is that defined? You know one person prefers a rational method, one person prefers a (off mike).

MS. LORENG: Oh, I would just say that QSR itself talks about requirements, specifications, iterative process, design review, validation, risk assessment. So I -- what I try to do is, since it's a software talk, I try to say design controls and how -- and software development principles would -- you could say they're your SOPs too for how you're going to develop it. But --

SPEAKER: Yeah, Chris Fletcher (phonetic) from (off mike). And yeah, basically it's all around fitting your software development process into what the FDA is looking for, the things like designing tools, designing

plan, design outputs, verification, validation and (off mike).

No matter what particular process you're following, a particular method, or a structured method, whatever, you still develop those kinds of products and they still fit into the design controls of the FDA. Is that answered?

MS. LORENG: We don't -- we don't endorse one development-type model, if that's what you're getting at.

SPEAKER: No, no, that's not what I'm getting at.

SPEAKER: And let me try it in another way that might make more sense. And I think that from what I heard you say is that it's kind of like a CobiT standards inspection, in that you have to have your software development method documented, and then the FDA is going to come in and test it against your method to make sure people follow. Is that what I'm hearing? And the FDA doesn't say you have to do it this way or that way or the other way, they're saying --

SPEAKER: And against the QSR, I mean new development has to meet -- be in compliance with the QSR.

SPEAKER: My question to these folks is, is that that clear enough defined from a software development methodology, in your mind -- because I've never done it, so.

MR. DODDRIDGE: I suggest that that may be good cocktail information that you can discuss with the members. Thank you.

Our next speaker is Tammy Poling who works for Sunquest Information Systems, but she is also a member of the AABB Information Systems committee, and I believe will be speaking on behalf of the committee.

She is going to present the results of a survey that ABC and AABB conducted of independent blood centers, hospital blood banks, and transfusion services. The survey questions were developed by the members of the BECS Conference planning committee, and included several staff from the FDA. Please welcome Tammy.

(Applause)

MS. POLING: Good afternoon. Do you hear me okay? All right. As we said, we -- I'm going to start with giving you some survey results that we did as a team. We developed the survey as a planning committee. The

survey was distributed by ABC, America's Blood Center, and AABB, and we distributed in June of this year. The ABC sent the survey to their members, and AABB sent it out to their transfusion members.

They divided it up, AABB divided it up to their hospital blood banks and their transfusion members, and then ABC sent it out to the donor members. We sent it out and collected the responses. We are linked to a website survey software.

Of the 75 ABC members that we sent to, they received 63 responses, which was an 84 percent response rate. AABB receive -- sent out over a thousand surveys and received back 312 responses. While this is only a response rate of just over 30 percent, for AABB that tends to be a pretty good response rate, to be honest. They were actually hoping to get between 15 and 20 percent back and they received over 30 percent. So as far as the AABB goes, they actually got a pretty good response rate for -- on the survey. With that many members, it actually is kind of tough to get back a really strong response rate.

So the ABC members, so again this is the larger donor centers, your ABC members; 38 percent of the

responses were from members that drew less than 50,000 units, 32 percent were members that drew between 50,000 and 100,000 units a year, and then 30 percent were over 100,000 units. So their responses were divvied up pretty good, 30 percent almost equivalently between -- almost equally between 30, 30, 30, the different-sized collection centers. And over 94 percent of them used a computer system. So that's probably a good percentage, and that's where we would respond. I don't think there is a whole lot of people who are still manually out there.

And I'm hoping those are the really small ones. Sixty -- 73 percent of them said they are on the latest version of their software, 25 percent of them said they are not on the latest version and 2 percent of them did not know.

Of these survey respondents, these are the users. Again, these are the ABC respondents, 35 percent said they use BBCS, 29 percent WinGate, 10 percent SysTec, 8 percent Mediware, and then a variety of others. And again these are just the people that responded to the survey. This is by all means it's not a --

SPEAKER: (Off mike) respond. They didn't want

to --

MS. POLING: Again, this is not a complete list of donor software vendors. This is just the people that responded to the survey. The ABC-responder profile, we asked them how do you use this software. And this is the top uses. Obviously, there are a whole lot of other uses that both Rodeina and Angus have covered today, but this was the top uses that came in. The primary use was donor management, component manufacturing, inventory management testing, donor health history recruitment. These all came up in the top 50 percent of uses for their software.

Eighty-four percent of them received their IT support internally. Their validation: 89 percent performed validation both by the IT department and by the users, 8 percent of them had their validation performed only by the IT department, 3 percent did validation by the users. No one that responded to the ABC survey had validation performed either by -- either with vendor assistance or by an outside consultant.

Okay, the AABB respondents. So these are primarily transfusion centers or hospital-based donor systems, so they are smaller donor centers based on a

hospital. This was not divvied up so well. I guess, we didn't give them as good a range. 70 percent transfused less than 10,000 units a year, 29 percent was 10,000 to 40,000 units a year, and then only 1 percent was greater than 40,000 units a year. Again, about the same, 95 percent used a computer system. Only 53 percent are on the latest software, 38 percent are not on the latest version, and 9 percent of them are just not sure.

And here's the breakdown of users and what software they are currently using. And again, we have some other brands there. But again, this is not just a list of every transfusion software out there, but these are who responded to the surveys. And again, the primary functions; we receive back transfusion management, component manufacturing and testing, and again there's a -- with a whole lot of list of other functions they do. But this was at the top of the list.

Seventy-nine percent received their IT support internally, 40 percent did their validation both by the IT department and the users, only 4 percent had their validation done only by the IT department, 34 percent did their validation only by the users, 11 percent was vendor

assisted, and 10 percent was done by outside consultants, which is very different than what we saw from the donor centers, seeing that almost 20 percent had outside help with their validation. And I'm thinking a lot of this probably comes by who does the IT support, thinking that probably in a transfusion center service, we're going to see a lot of the IT support coming from LIS department that only does part-time transfusion support or even a hospital-wide IT department that again is only giving part-time assistance to the transfusion system. So they're going outside to get their help probably with the validation and putting more money into outside assistance.

Okay. So now, I'm going to read you some of the questions we actually put out here for them to get a feel more for their view of the 510(k) process. Since we're here today discussing some of the advantages, disadvantages of the 510(k) process, we wanted to see as a committee, what the view of the industry was.

So one of our first questions was does the requirement for the FDA 510(k) clearance limits the number of software vendors willing to enter the market, forces them to assume regulatory liability that outweighs the

revenue potential that may derive from the software product. Then we asked them to scale this; "This greatly helps my facility/somewhat helps my facility/has little or no impact on my facility/somewhat hurts my facility/greatly hurts my facility," or "I completely disagree with the assertion."

Now, the first row is the ABC members, and then the -- again, the AABB members were grouped into either transfusion services members or hospital blood banks. The hospital blood banks or the small hospital donor centers, this is how AABB divides up their membership. And so you'll see, for the most part, we have a little difference between the AABB members and the ABC members.

The ABC members tend to skew a little more towards "Somewhat hurts my facility." The AABB members are more "Little or no impact." And if you go to the next slide, you get more of a graphical representation where you can see the ABC members are slid a little bit more to the right, while the AABB members, both of those graphs are "Little or no impact."

The next question we asked them, FDA regulation of BECS as a medical device in general and 510(k)

clearance in particular, improves the safety of BECS software on the market. And we have pretty much down the line "Somewhat helps my facility." Now this is one of these questions where I really didn't expect to see much in the "Somewhat hurts my facility" or "Greatly hurts my facility" column. I can't imagine anyone would say the safety would hurt their facility. We were kind of more interested in, you know, how far towards "It helps" or "Little impact" or even "Disagree" would -- what would fall into there.

For the most part though, we did get a pretty strong 50 percent response down the row in "Somewhat helps my facility." And so graphically, that's where we see that.

The question as to whether the 510(k) clearance slows downtime in the market for improvements and upgrades, and contributes to blood centers maintaining older and antiquated systems. We got a little skew to "Somewhat hurts my facility," and a little higher on "Greatly hurts my facility" for the ABC members. You don't see that so much on the transfusion side. Though you do have a 10 percent of the ABC members disagreeing

with the assertion, and this is another one of those where you don't expect to see much on the "Helps my facility" side. So you'd -- you know, I'm little surprised to see much there at all. And again, just a graphic representation of that for the visual folks out there.

The FDA 510 clearance requirement increases cost for the vendor that are passed to the consumer through increased product support and implementation costs. Again, we don't have -- we have a little skew to "Somewhat hurts my facility," nothing amazing or strong either way. Another one of those; I wouldn't expect a lot of skew to the left just because of the wording of the question. You wouldn't expect anyone to really say "It helps your facility."

But everyone seems to be falling in line. So these last couple of questions, you don't see much disagreement between the donor -- the donor systems and the transfusion systems.

FDA ensures processes are in place for the vendor to notify its customers in the event a significant safety issue arises with its software. Again, you see a pretty strong left movement here though; "Greatly helps my

facility" and "Somewhat helps my facility." And you don't even see a very strong disagreement with that. So everyone pretty much just to the left on that. And again, you see a pretty good agreement between all the surveys. The current regulatory scheme limits the integration of third party software to BECS. Interfaces must undergo medical device 510(k) clearance. This is actually an interesting one because we really did see a strong difference between the ABC members and the AABB members. You see the ABC members, that 40 percent, in "Greatly hurts my facility." And I think that may be a difference between the transfusion software, is really only interfacing with the LIS systems and the --

SPEAKER: (Off mike).

MS. POLING: And the -- yeah, and the -- and the donor systems are trying to interface with other systems. But the transfusion systems, really, it's the LIS systems that are trying to go outside, and they don't have to get the 510(k) clearance for the LIS system to integrate. And so I don't see the transfusion systems so much, needing to get the integration or the 510(k) to integrate.

So if you look at that graphically, you see the

huge difference. Okay, we had a couple -- actually, did I skip a note? We had a couple of true or false questions. The FDA requirement for 510(k) clearance helped to reduce the number of bugs in the software prior to release to market. The blue is true, and the red is false. So for the most part, the ABC members were kind of 50-50 on that, but the transfusion members pretty much, 65 to 40, or 65 to 35.

Do you believe that 510(k) clearance helps reduce the number of bugs in software prior to release to market? And then the FDA requires BECS software vendors to have quality processes in place to ensure a minimum level of safety and quality. And that's 90 -- 90 percent difference, and pretty much straight across the board.

(Applause)

MS. POLING: Yes, sir.

MR. BIANCO: I am Celso Bianco of the America's Blood Centers. Just a couple of questions we're trying to gauge. Who were the people at each of these institutions that answered the survey? We got to cut down with the cost or something like that, we see a full -- with kind of very different answer from the quality department.

MS. POLING: It varied. We sent it to -- for AABB it required -- it depended on who the contact person was. And we did ask that question on the survey and I didn't have it here to present on the slide. Most of the time at the AABB -- on the AABB survey, most of them were transfusion services supervisors. At the ABC, I believe, most of them were IT people.

SPEAKER: IT quality and the AABB --

SPEAKER: Yeah, and --

MS. POLING: IT --

SPEAKER: -- and the second of these clarifications that you see in terms of the four centers that have their own systems, those are exactly the 6 percent. You said 94 percent said "yes, we have a computer system," and that 4 didn't have any type of computer system. Could that be a confusion that those were the 4 that had in-house systems? And I believe the question was great because I cannot believe that a blood center to date doesn't have a computer system.

MS. POLING: Could that -- could be, okay, yeah, it could be.

(Laughter)

MR. DODDRIDGE: Any other questions?

Okay, thank you, Tammy.

I would like to take a 15-minute break, and I want to again emphasize that if there's any questions, Bob will be taking those questions. He'll be roaming around this room and probably out in the foyer. So if you see him, please give him those written questions. One of the things I was amazed that there were still, what was a 4 percent that did not have end-user validation; they had their IT department do the validation, I hope that was a mistake.

Okay, well, Jeff will be giving us a wrap-up right after the break. So we're going to take a 15-minute break and be here in just between 1:00 and 1:05 or 2:01, I'm sorry.

(Recess)

MR. DODDRIDGE: We're about to get started again if everybody could come on in and take their seats?

Can we please take our seats if you are in the back of the room, then we'll get started?

I'll turn this off before we start it.

Okay, we're going to start the next session with Jeff McCullough. Jeff will be -- I've seen him taking

copious notes over there. So I'm sure he's going to have a lot of points for us to consider this afternoon.

Jeff, I do appreciate you putting this conference over your African safari. I understand that you were to be over in Africa, so we appreciate you making the sacrifice, so Jeff?

MR. McCULLOUGH: Thank you very much. And at least, I won't attacked by elephants or something here, but maybe attacked by some of the audience. I don't know.

SPEAKER: Yeah.

MR. McCULLOUGH: I had to, I guess, with mixed feelings, thank you for inviting me. It's been an interesting day so far. I think as most of you know, I don't do this on a daily basis. And so I'm probably the least informed person in the room which may be to some advantage. And I apologize upfront if I'm asking some rather naïve or inappropriate questions.

But I have been able to jot down some things that occurred to me as the discussions have gone on. And so what I like to do is just start to go through these. And this isn't intended to be a presentation, because I'm going to ask you to join in with the discussion or

consideration of these issues.

And so it seems to me starting with some of the larger issues; first point I have here is to what extent has the situation changed in approximately the last 15 years or so since the regulatory approach was applied. Some of the discussions have implied that the -- certainly, the technology has changed, but some of the discussions have implied that the level of expertise has changed in blood centers, or other things have occurred in the environment, which would cause or enable us to think in 2008 terms about the way in which these systems are regulated. Would anybody like to say anything about this?

Rodeina, maybe you would? I don't mean to put you on the spot, but I want to have -- why not.

(Laughter)

MR. McCULLOUGH: I think you did allude to this at least in your discussion.

MS. DAVIS: (Off mike) I think I did, and want to add that probably it wasn't too clear what all of the presentation this morning is. And firstly I think -- this presentation is still at the maturity level of the IT folks in our blood center, who do we have? And the

maturity of the level of understanding the technology and really understanding the complexity of what are the blood banking functionality are, as well as the knowledge and the system that are in place regarding validation.

I do support what the discussion early this afternoon regarding we do have the FDA go to a software vendor and look at their older design culture. It is the vendor role to look at their own cycle through and make sure that they do it right, and they are following the proper methodology. I think when we were in 1990 as I witnessed during the change of the past 10 years within IT, we came a long way as an organization, understanding the technology, understanding what we need to do. And I think we need to look at this point, how can we as an industry, work together to get the best out of everything we have, versus -- or spinning our wheel in trying to do something and stepping on each other without getting the result that we need. So I leave it open if any other folks want to add to this.

MR. McCULLOUGH: Okay, well, thank you. Let me, I guess, in the interest of time, I'm going to have to go through these little more quickly than I had planned. But

it seems to me that several issues surrounding this whole point that are illustrated here in it; does this regulatory approach help assure or improve blood safety?

And is there some evidence or suggestion that quality and safety has improved as a result of this regulatory environment? So I'm not sure that we have any answers to that. I'm sorry I don't remember, one of the speakers showed some data about recalls and that sort of thing which seemed to suggest that they weren't much different today than they were pre-regulatory, which maybe that's good news or bad news.

But it seems to me that where we've to start is, is this regulatory framework improving blood safety and helping patients. Secondly, a number of speakers -- and there's a sort of a general toeing in the room that the big -- the big guys don't play in this game; IBM, or Microsoft, or others. And there is another -- these are various ways of referring to this, that it's a niche market or there are unlimited number of options.

So my first question is, does it really matter that Microsoft and IBM aren't in the business, number one. Number two, is this really a niche market, or is it just a

modest-sized market when one thinks globally. And I'm not sure I'd really think of it as a niche market so much as there is a finite size to this market, as there is for most things that we sell to blood systems.

And so there's lot of discussion that the current limited choice is a risk, at a limited number of vendors. One of the slides again, that someone showed that something like 37 percent of the clearances were with four companies and the other 67 percent were with 41 other vendors, 18 of which had only one clearance.

Well, that's a lot of vendors. It would suggest there are at least four fairly substantial vendors, which is two more than the vendors for NAT reagents, by the way.

(Laughter)

MR. McCULLOUGH: And so I want to mention that as an example, clearly these systems are essential. You can't go down on these systems and begin to function. On the other hand, we can't go without NAT reagents further so and continue to function. And as you know, we can't substitute the other manufacturers NAT reagents, because the devices and everything else are designed for that particular system.

So apart from that as an example, I'm not sure if we think of plastic bags, or are there other five or six global manufacturers of plastic bags, also blood taping reagents. So I'm not sure -- I don't know what the ideal size is for the number of vendors that would be ideal in this field, but it isn't obvious to me as a new kid on the block that the number of vendors that are there now is somehow a limitation or a problem.

So it might be something for similar discussions. But if -- one of the implications is that the -- well, final implication pretty clearly stated that the regulatory environment prohibits more vendors from entering the field. But if we already have twice as many vendors as we do for NAT reagents, and about the same as we do for making plastic bags, the question is while it's a disaster, if one of these systems goes down and the blood center can't operate, is this really that much of a threat if we have four, five, six really solid vendors.

So we'll continue with that. But -- well, one other point along those lines, for instance, with plastic bags if or when the Avian Flu pandemic hits, so we'll probably be out of plastic bags before it ever gets to

United States because they're all made in other parts of the world. So I'm not so sure the number of vendors is as bad as it sort of been implied here.

It would be, I think, very helpful to have some more discussion, and I'm really sorry I don't remember all -- the particular speaker's name, I think it was you Joan, right? You had two or three really nice slides where you compared the pharma versus blood systems, processes, and how your view is that there is such a fundamental difference about the way the software functions, that it's appropriate to have regulatory differences.

I think that's an issue that would really be very helpful and would benefit from further thinking or discussion. I don't mean to disagree with your slides, but it seems as if that's one of the things that's at the heart of some of these regulatory issues.

If one is trying to find global harmonization of regulating software, and the U.S. is different from everyone else, it would be helpful to have more discussion about the basis for the thinking of the United States versus other regulators, and maybe there isn't a way to harmonize it, but that -- those were really nice slides

and it would be a nice basis for more discussion.

The other point on this slide is the -- I liked, I think it was you also, the white and the black box, and that's another area that would benefit from discussion of clearly most blood establishments will not have the expertise to really review what's in the vendor development process, and therefore it does become a black box.

Does this matter and is it realistic to think that blood centers would probably not, so is it necessary for anybody; and if so, it makes sense that it would be the regulators, but to what extent is it important to be able to analyze what's in that vendors development system, and what's in that -- what is the black box to most of us.

A couple of other comments here, one of the concerns has been that the regulatory environment inhibits technologic advances and that it prevents us from implementing cutting edge technology. While -- and I concede that of course, we all want to have cutting edge technology, my question is to what extent do we need cutting edge technology.

To what extent are we getting caught up in the

guys that used to hang around in my fraternity in college who every time there was a new speaker system that came out, they wanted to get the new speaker system because it had one more refinement in the sound system that it was providing, but when you sat and listened to it, you couldn't tell one bit of difference in the sound system.

So it may be a dumb analogy, but of course, they are extremely creative people in the technology industry, and the technology is going to constantly evolve and change. And so I think it's really more of a thoughtful management decision about how important it is to evolve and change a lot, just as along with that, versus how much can we stabilize and standardize what we do and go through generations of iteration which leads me to also suggestions for the agency to consider.

I'm not sure where it is on this list, but there has been some discussion about whether there might be ways that the agency could either provide more information or more guidance or somehow streamline things so that when there are really valuable enhancements or technologic enhancements that are appropriate to introduce that this could be done in a reasonable and realistic way. And it

seems to me one of the -- if I could just make an aside or comment, that one of the wonderful values of today and tomorrow is that you're all here.

I gather that this kind of dialog has not occurred much at all, and so hopefully, ABC has taken a wonderful leadership position here in beginning to foster this kind of dialog because it's bound to be helpful to move things forward.

A couple of other points here; deciding when to submit -- a couple of people mentioned that we don't know when to submit for an enhancement. Well, can't you call up the FDA and ask them? Maybe, I comment this from a different -- I know I commented a different view because a lot of what I do these days is dealing with novel zygotic therapies of stem cells or tumor vaccines or things like that.

And this is a new regulatory arena for the FDA, and we talk to the FDA all the time. And often we call and ask them how they think about regulating something, and they say we don't know and we should talk about it. And there are regular meetings where various investigators and key FDA individuals meet and talk about how to address

these sorts of things. So maybe one of the outcomes of today will be some more of these kinds of sessions where this kind of dialog can occur.

Another point was made by somebody that it's very difficult for newcomers to submit, is that bad? You know, I'm not sure that I want to operate my blood center with a newcomer. So if a newcomer has so little expertise that they're not sure how to go about this, maybe there is a lesson there. I'm not sure that's a disaster.

There are a number of comments also about -- which seemed very appropriate, about how to interface these systems with other systems. And I have two or three other slides which I wanted to show, but the way I think about all this is, the central thing to me is the control of the manufacturing process which also means qualifying the raw material which are the donors.

So the donor evaluation and donor selection, all the manufacturing process, but there are different aspects of this from that. There's the management aspect, there's the business aspect, those sorts of things, which I think of as different. And then also, if you're trying to interface with the hospital transfusion service and the

computer system there, these are challenges.

And ideally, the systems will fit together and -- but it seems as if this also could benefit from a dialog with the vendors and the blood systems, and the FDA, as to how one can enhance those integrations, but yet find a line, where one has moved over into things that really don't need regulatory scrutiny.

Well, I think maybe I'll just comment on the last line on this slide. I think it was our colleague from Scotland who also points out that we may also be contributing to the situation. And I just end with one little anecdote of when I was at Red Cross national headquarters a lot of years ago, we -- in the '80s we had BMIS, the Blood Management Information System, which was an IBM system that we'd in about 20 of our centers at that time.

And we had IBM all programmed, all planned; they had committed to develop a single comprehensive system for the Red Cross to roll out, and they were going to do it at their cost and make it a donation to the Red Cross. But a month after I left Washington to go back to the tundra in Minnesota, the IT folks at Red Cross convinced Ms. Dole

that they could do it as well or better than IBM, and I think IBM excels in the market.

So you know, there are probably are a lot of ways in which we're also a part of this situation, and maybe the best outcome from today and tomorrow is that this were just one of the first of many of these kinds of meetings where some nice progress can be made. So I'll try to hang in there and do what I can over the next day or so. That's it and thanks.

(Applause)

MR. DODDRIDGE: Jeff, I thank you for giving us lot of points that we can take to those breakout sessions, and hopefully there we can find some answers to them. We do have -- I hope you've all picked up your slips for the session that you would like to go to. If you haven't, I'm sure Laurie may have some extras in the back, or I would suggest you just find -- follow one of the packs going out of here and find your room.

I'd like to ring up the leaders now, if you have a slip for topic one, Mark and Eva. Would you hold up your hands, where's Mark and Eva? Mark's in the back, well, that will be in Severn, which is across the hall to the

left, I believe. So those that have had topic one, if you'll go ahead and follow Mark. We'll try to get one group out at a time, and see if that will work.

Okay, we have group two; Galder (phonetic) and Tammy, would you hold up your hands. He's Galder, Tammy? They will be in the Annapolis room which is down the hall on the same level. We need to, like these tour guides overseas with their little umbrellas or the banners that they wave. If you're in group three, Katherine and Gem. Gem is right there, he's hard to miss there. Gem will be taking you down to the assembly room on the mezzanine, which is one level below.

And last but not least, we have our group four with Mary Beth and Becky, right over here on the end. And they will also head over the council which is also on the mezzanine level. So if you're in group four, follow Mary Beth and Becky, and that will be down on the mezzanine level. It's one level --

(Recess)

MR. DODDRIDGE: If we could find a seat, if all the sessions are over we are going to try and get started. Bill, do we know if all the sessions have ended?

(Pause)

MR. DODDRIDGE: Okay, I see our last group has arrived, so I think we'll try and get started. Could I have your attention please, and let's try to start the session. I did take the opportunity to go to all four breakouts, and there was a lot of lively discussion going on. So I think we are going to have some good discussion that as each of the facilitators come forward and give us a review.

The format will be that we'll have each group come up and give about a 10-minute presentation today. so our first group to come up is -- will be on the issues in applying medical device quality systems, regulation to contemporary software development. And Mark and Eva, who is going to give that presentation?

MS. QUINLEY: I think got the stuff with --

MR. DODDRIDGE: You think you got stuff -- oh, he is following you.

MS. QUINLEY: So I do it from here, is this okay?

SPEAKER: Bob is that okay or do you want to --

MS. QUINLEY: Oh -- you want it up there --

SPEAKER: Go up to the (off mike).

MS. QUINLEY: Well, our topic was issues with the applicability of the QSRs, and one of the things we found out right off the bat that it's not so much the regs, but it's ourselves that are the issues in many ways. And so some of the things that you will see we discovered are actually because we are blood bankers and we are kind of set in our ways.

One of the questions that Mark brought up was, how do you feel the applications of the regs affect the development of software, and one of the things that came up was that it's very important that you engage your customers in the development, so that you get the requirements right.

The regs want us to have a list of requirements and really sometimes we can't have that list complete until we actually get into the development. So it's important that the vendors work with the customers to do things like have user groups, look at industry trends, have advocates within the vendor staff that are actually blood bankers who understand the process, and use focal groups as much as possible.

One of the things that came out here though is that often times there is new technology that come out --

that comes out, and we are very slow to implement that because we are not comfortable with it.

The Internet was brought up, for example, but it took years to be comfortable with that both from the FDA's standpoint and from our standpoint as well. So that's one of those areas where the issue is really with ourselves, and our comfort level of a new technology.

The other thing we asked, and then we had lots of interest in the room, which was great was how do you view the regs from a competitive nature, and here the statement says it all. If you want to apply the -- if you want to get in the game you got to play it by the rules. And so these are rules and -- quite unexpected, I guess, I didn't expect this.

There was a lot of positive about the regulations that they felt without those regulations we would have crappy software that was a terminology that was used. So that it is important.

The users though that were in the room had a little slightly different view, they felt that it impeded us getting something very quickly. Because often times you had to you know go through the requirements, the hoops to

get something quickly. So we came up with this issue about interfaces, and we talked a lot about what if we had a standard interface.

And from our FDA folks that were in the room, they said well, if we had a consensus standard certainly that would be something that they might approve the entire thing or they might approve part of it. There's an issue there though because of the proprietary nature of many of our vendor's software. So that's an issue with the applicability of the rules that came up.

Another thing that we talked about was there's a lot that goes on in the software that really is not critical to the outcome of making sure that unsuitable product doesn't get out the door, or that the donor is not harmed. So do we have to do the clearance on everything.

And many of the people in the room brought up, and I think rightly so, well, how do you segment what you are to put through the clearance and what you are not. And you are going to limit, actually it's going to limit the vendors in their marketability of their product if they do that.

Around this consensus standard though there was a

lot of discussion about if we were to do that how would we go about doing that. We brought up ISBT and we all know how quickly we got that, so --

(Laughter)

MS. QUINLEY: So there was a lot of discussion about what we should do, if we should have ABB convene a group, and then the vendors brought up, well, the market is international now, and so we would have to ensure that whatever group convened that would have representation from the globe because that's where the marketplace is spread to.

There was also a question about if blood banking were very sophisticated, and we had very sophisticated internal external vendor audits, would we even need these things, would we need these regulations. And the answer was yes, because we don't want a lot of different people coming in and doing audits of us, it's much better to just have the FDA come in.

And I thought that made a good point. Now, one of the vendors that was there, said they had 12 different vendor audits in a very short time period, which I would tell you would drive me nuts.

Anything else Mark that you can think of. I have a lot of notes here, I write a lot of stuff. I think that's pretty much it, that we came up with -- it was a good group that we had, we had vendors, we had users, we had a lot of people that were very opinionated about the software, and very passionate about it. So we had some really good discussions.

MR. WEISCHEDEL: You know, I would -- this is Mark Weischedel, CIO of the American Red Cross. I'd add that there was a great deal of energy in the room around standards, not -- as you might imagine when you talk about standards in technology there was not consensus on what to do, when to do it how to do it. There wasn't really consensus on much of anything really. But --

(Laughter)

MR. WEISCHEDEL: But the standards are very much needed, and it's something that is probably long overdue in our industry, and a great deal of interest in moving forward. And other than that I thought -- by the way, I am from Philly and Eva is from Tennessee, I really thought you'd enjoy her accent more than mine. But I'd be happy to take any questions.

MS. QUINLEY: Thank you all.

(Applause)

MR. DODDRIDGE: Our second group topic was to identify the top barriers and advantages of a FDA 510(k) clearance in the development of BEC software. And Gouter and Tammy will be giving that presentation.

GOUTER: Thank you. You know, I actually put a small little presentation here, so let's see. We had a great group. See that --

(Laughter)

GOUTER: No cholesterol, no flak (phonetic), easy flow.

(Laughter)

GOUTER: You know, we had a really vibrant team, we had users, we had vendors, and we had FDA. We had a lot of exciting discussion. We didn't even know how time went by, so in the last two minutes we were trying to cover up and come up with the things that we thought are important to share with this group.

So here it goes. This is a consensus of our team. Our topic was five top barriers and advantages that are associated with the 510(k) process. The advantages and

barriers. Number one --

TAMMY: The number one advantage, to the 510(k) process is --

(Laughter)

TAMMY: Improves quality and adds assurances of quality.

GOUTER: Number five, the last barrier --

(Laughter)

GOUTER: Negative experiences cause ripple effects.

TAMMY: The number two advantage to the 510 carrier -- to the 510(k) process, it ensures the processes are followed.

GOUTER: Item four barrier, false sense of security for some users.

TAMMY: The number three advantage, keeps vendors accountable.

GOUTER: It certainly creates a closed system.

TAMMY: Number four advantage promotes getting bugs fixed.

GOUTER: Interfacing and integration of satellite systems with the 510(k) system becomes complicated.

TAMMY: And the fifth advantage is that it ensures common minimum standards.

GOUTER: Of course we have been talking all day in every presentation 510(k) process does up bring the cost and also has the time factor with the process. So not only we talked about the advantages and barriers. The more we talk about -- okay tell me some advantage, but we kept talking neither advantage nor barriers. So then we thought it is important here to share what other ideas our team came up with.

That would help the process is streamline the 510(k) process. So meetings like this going forward, some kind of a workshop, some kind of a platform where we streamline the -- discuss about how the 510(k) process works and streamline it. Gather more data to determine effectiveness of 510(k).

So we tried to come up with the barriers, and the advantages without having enough data not evident it is hard to quantify those opinions, better communication with, among from users to vendors to FDAs, in that 300-day cycle we need a better communication.

And the process is hard. Sometimes we thought

it's a -- it could be a perception getting 510(k) a review process, getting 510(k) clearance, so we think process is hard, so the team felt that they could be sometimes as a perception. That's about it, any questions for us? And our team was great, thank you for everyone who participated in the team.

(Applause)

MR. DODDRIDGE: Now, that sounded like David Letterman's top ten list there.

(Laughter)

MR. DODDRIDGE: And we got a little tech savvy there going on, is it like the two groups, I want to see if you could beat that, that is the only PowerPoint we've had so far. The third group is the impact of FDA's medical device approval process, and 510 clearance on blood safety, and that was Kathleen and Jim. And I believe Jim you are going to give the report?

SPEAKER: (Off mike). Do you have anyone --

MR. MacPHERSON: Oh, no this is low tech. This is low tech, sorry. Well, our topic was some what -- oh, let me get rid of this, that's a distraction here. We'll go back to the desktop. Our topic was -- oop -- similar,

in the impact of FDA medical device approval and 510(k) approval on blood safety. But we were able to dispose of that topic fairly quickly.

Because there was a general agreement that, and probably not for the specific regulation of the computer systems, but the integration of requirement for quality systems in the early 1990's on blood products on the blood establishments. That had a huge impact that rippled throughout the entire organization, and certainly as far as computer systems, but in all systems, in all processes.

So the application of the quality systems, everyone agreed it was extremely important. We also agreed that we are not -- it's not that we are regulating the wrong things, or not having to paying attention or having standards to the wrong things. In fact we are probably measuring or looking at the right things.

The question was process. Are we reusing the right process, are we using the most efficient process, are we using a process that has kept up with the time as opposed to a process that may have been put in place 15 - 20 years ago when the situation was much different, and the players were much different than our level of

sophistication was much different.

And I think that's where we had a lot of different thoughts and different ideas, which I will try to go through some of that, and it's all going to be verbal but. I think we -- there were some discussion and I can't say there was agreement. There was discussion as to whether we -- whether the issue is that the 510(k) process itself is a problem.

You know, should we be going to a system that's similar to what the Canadians or what the Europeans use, and putting the focus all on the end user, the blood establishment, and all through validation, but measuring the same things as opposed to the 510(k) process. But if we are going to continue with the 510(k) process, how can that be simplified.

And could it be simplified even to the point of similar to CE marking to Council of Europe marking. Where it's almost voluntary but the same things are required in terms of the vendor to provide all this information and then -- and invalidation is based up on the disclosure of all that kind of information.

The theme though that we talked about through

most of our discussion was opening options. You know, the options because what we have in place right now is a barrier to upgrades, is a barrier to change. And that we are using the -- it was pointed out we are using the latest accounting system.

And we are using the latest HR tracking system, and we are using the latest of this system and that system, but when we get to regulated systems, the systems are far behind what state of the art, and really that's our core business. And that's what we are doing, yet we are not using the best systems out there.

And it isn't the vendor's fault. Jeff McCullough asked the question, you know, was four vendors enough, and the other question that was asked is, is this the right vendors. Why aren't we, you know, we have blue chip companies as far as providing us with math and serological testing, but where are the blue chip companies when it comes to a computer systems.

And -- or will we always have niche players, because we are such a small industry that there is a barrier to the market that the large manufacturers will see we're too small, and too specialized, and they may stay

away. It's not clear how much of the small market is the barrier versus the regulation.

Clearly the regulation is a barrier because the vendors will say that, if you talk to a Microsoft if you talk to SAP and they just say they don't want to get into that because they don't have to, and make money. And yet at the same time we are a small, we are a very small market. Even worldwide we are very small market.

So I think that's an issue. I think those are the top issues that we talked about. There were lots of specifics that we talked about. There were some discussions about the fact that there is a lot of variation from country to country.

You have a lot of national systems that are lot easier to regulate. A national system that uses one computer system versus in the U.S. where you have over 200 -- 250 organizations collecting blood, on the other hand you have the 8020 rule. And with 20 percent of the players collecting 80 percent of the blood, and the question is are we regulating to the lowest common denominator, and to the disadvantage of the larger organizations that are being slowed as well.

And let's see. See if there is anything else that was mentioned -- any body in my group want to add something -- oh, an example of -- in terms of is the 510(k) process is a FDA barrier, and Rodeina gave the example of -- she's been working with a number of other blood centers and a number of companies on application of our FID to tracking blood from donor to patient.

And it's very feasible perhaps eventually economically feasible, but certainly systemwide it really lends itself to what we do, and yet the very companies that are the experts in this area. Once they were told they would have to potentially go through, and that there is no final decision on that. But potentially have to go through 510(k) approval has said no, we are not interested in the market if that's if we have to subject our self to 510(k).

And I think one vendor said that the 510(k) process was basically a waste of time that they could dummy up the process and fool FDA except maybe for the inspection. But that the system itself could potentially be fooled. There was a question of whether there are far more standards available today than there were 15 - 20 years ago, and the ISO was mentioned that the fact that

most of the vendors to sell in European anyway have to be ISO certified in addition to the CE marking.

And you know is that sufficient at this point, and something that we should look in terms of harmonization. I think that covers it, anything else anybody can think of --

SPEAKER: (Off mike)

MR. MacPHERSON: Pardon me.

SPEAKER: (Off mike)

MR. MacPHERSON: In -- yes the -- again a simplification of the in-house developed software. You want to make the point Rodeina?

MS. DAVIS (Off mike): -- well, I thought you were --

MR. MacPHERSON: Well, I yeah -- but I'd look at my notes, and it just says in-house development. And I am not sure I captured the points you wanted to make.

MS. DAVIS: I think the question here whether we would be able to have in-house developed software. Where that software can be run under the license of one blood center although that blood center to enter state commerce where they have such as (inaudible) or Red Cross or you

know, blood center where you have different chapter, or different offices across the state, but you still developing your software.

It is your own software, running it for your own organization under your license. Is that a potential not to have need for a 501(k) for in-house developed software.

MR. MacPHERSON: Oh thank you. And also the fact that there will be notification of changes and inspection would be based upon how many changes you made over the last year -- even looking at that as a possibility. And I think we are done. Thank you.

(Applause)

MR. DODDRIDGE: I don't suppose that software vendor would like to raise his hand.

(Laughter)

MR. DODDRIDGE: Our last speaker today is and the last topic is to identify validation and documentation strategies for BACS, and that will be Mary Beth and Becky. So come forward, please.

MS. BASSET: Well, there was no lack of discussion passion or questions around the topic of validation. We had more questions than we had answers for.

There seemed to be lots of confusion, and you would have believed probably that since we have been in this validation business for as long as we have been in. That we really wouldn't have had so much confusion, which just tells us that we need some more information.

So our approach was to create kind of a list of questions, the hottest topics people could think of that they really want it to address. We tried to prioritize those questions, and then went into our discussions. We had representation from the FDA from vendors, from transfusion services from blood, the blood industry and from the plasma industry, so we were really very well covered.

So our first question that we asked was, if the 510(k) process was changed, or removed what would be the impact on the end user for -- regarding validation. Now, we had lots of discussion about whether or not 510(k) ought to be removed, what that process should look like. And then we decided that that really wasn't our topic we were to talk about validations.

So we decided not to render an opinion on that particular topic, but we did decide as a group, or

discussed as a group that impact would be very large. Validations would be increased for the end user. This would drive up our resources. It would drive up our money, it would cost more, it would take more time, and require more expertise, which this then possibly could impact the cost of blood.

Our second question was what clarifications do we need? This discussion really told me, and I think the group because the list was really long, that we really do need some more information and some more guidance. So some of the questions -- and I am just going to list them here. There was more than this, but I just kind of picked the highlights.

What is meant by validation strategies, what is that extent of validation needed when software is implemented at multiple sites? Confusion of what is meant by IQ, OQ, and PQ. And I really supported that because I looked at a multitude of presentations on this topic, kind of just trying to prepare myself. So I looked at presentations that industry had given, FDA had given, plasma, blood centers, and there was a real variety of definitions around those very topics. So it just does

point out that maybe we do need a standard definition that we can all wrap our hands around.

What validation is required to the modification of off-the-shelf software? What is the extent of revalidation for operating system versus changes and packs -- and patches? To what extent can we rely on what the vendor has done and how much documentation is enough? So that just kind of gives you a flavor of the kinds of questions that got thrown out that people really didn't have the answers to.

And our third question was kind of out there. What would you change, if you could? What are some innovative ideas that we could come up with to present to this group that could have some thoughts for discussion? And I've got two of them listed here. And I really am going to ask couple of people that were part of the team because I'm not an IT expert. I really am just a quality professional.

And so they were talking about things that were kind of like up here for me. So the automated validation system and Robin, if you could just go to the mike and talk just briefly about what that is. This again is kind

of future kinds of things to do.

(Laughter)

ROBIN: Okay, well, so in automated testing, we're -- that's talking about using a tool that's written in a coding language that actually runs by itself. And it's set to run a set of inputs and the output would come out only if all the inputs were correct. And if it wasn't correct, then it would come out as incorrect. And we discussed using those kind of tools in the future.

MS. BASSET: Thank you. And then Tim, if you could talk about application service provider. Did I get that right?

TIM: Yes, sure.

MS. BASSET: Okay, I got that part right.

TIM: We were discussing -- thinking outside the box of things that would be game changers. And it's clear that the responsibility for validation is enormous. And the smaller blood centers have -- it's more difficult for them, they have less internal expertise and resources.

And what I suggested was maybe that the industry consider an ASP model where a single -- either a vendor or a single blood establishment validate a system. They

accept the responsibility for validating it for the hardware validation, for the disaster recovery capabilities, for all that stuff.

And then each of their clients then would have a much more minor validation for their own specific configurations. It might also help by -- convince people to standardize a little bit more, which would further reduce the burden of validation.

MS. BASSET. Thank you. And then the group went on to just come up with a few recommendations that maybe could be considered for the future. Because of all of the clarifications that -- and questions that came out of the group, they all believe that maybe a task force that was comprised of FDA, and vendors, and blood centers, plasma transfusion services, Canada, to all get in a room together and try to give us some kind of guidance on the lists of those things needing to be clarified.

And I'm sure there are lots of other things. But kind of all those people coming together to try to give us some answers and then to follow up that task force with a workshop that really would identify all of that information for us. And then, hopefully, that could

become our industry practice.

And then the third recommendation was gathering a better partnership between the industry and the vendors around validation requirements and what is really needed for the end user and to try to work together to define what that is. Maybe having a number of end users get together that are going to have to validate this system and really try to come up with the kind of guidance that we need as vendors or as the people that are validating these systems as to what is enough.

We had a great group. It was an active discussion. And I really thank the people that were part of that session. And that's all we had.

(Applause)

MR. DODDRIDGE: I think we've heard some common threads throughout these discussions on the four topics today. And Jeff may have found some of those. And if Jeff is ready, we will hear his report to kind of end the day today.

MR. McCULLOUGH: Excuse me. I'm sorry that the -- these first several slides are the same ones I showed a few minutes ago but larger. So I apologize to those of

you in the back of the room who couldn't see the first set that I showed. And I don't really plan to go back over these so much as to -- we have a few minutes. So I give you the time to attack me about some of the things I said earlier or disagree with them.

Maybe while you're thinking, Jay or someone from -- whoever you might think appropriate from the FDA, could you talk a little bit more about a couple of analogies that occurred to me that are maybe dumb ones and maybe don't apply? But the analogy of a pacemaker or a defibrillating device, where the device itself operates on software, but also I assume there is software used in the manufacturing of the device as well.

And is there anything from devices like that that we can learn that might apply to this situation? Maybe another sort of dumber analogy would be in aphaeresis devices, where you've got software that controls the device to some extent. Are there any analogies or do those not apply? Or --

MR. EPSTEIN: Well, my reviewers may wish to comment. But the general picture is that software embedded in a device such as an aphaeresis machine, which

we call firmware, is regulated. But it's regulated as part of the review of the device.

So it's not a freestanding software system. It's part of the device review. And the standards for regulating that software are pretty much the same thing. In other words, we're looking for all the kinds of validation documentation that we asked for for BECS.

Now, when you talk about software that controls manufacturing, I think that the critical distinguishing feature with respect to BECS and other systems at Center for Devices that are regulated as freestanding software -- there are various systems used in the hospitals, for example -- is whether they are providing data that is contributing to clinical decision-making.

And the concept is that the functionalities go beyond merely library functions. In other words, they're not just databases. They're not just indices. But that the software contains logic functions which are substituting for or augmenting a human decision that affects health.

So that's really the distinguishing feature because you can have very elaborate library-type data

systems that we're not regulating. On the other hand, you can have fairly simple logic systems that we would regulate because they're involved in clinical decision-making.

So it really just comes down to two things, that we believe that BECS, as a device, are systems that have high risk because of the impact of error on patient safety and which contribute to clinical decision-making. So that's the general framework. And it's the same framework at CDRH.

It is not simply because of control of manufacturing. And I think that that's the key misunderstanding. Yes, there are lots of systems in drug world where software controls manufacturing. But it's the clinical decision-making element. In other words, the doctor decides whether to use the drug. The software didn't help you decide whether to use the drug. It helped you manufacture the drug. But it didn't decide whether to use the drug or how to use the drug.

MR. McCULLOUGH: I'm going to skip ahead. I'll come back to some of these. I was surprised, actually, through the day that there did seem to be -- and I think,

Jim, you mentioned this or it came up in your session that I came here expecting that the FDA would be attacked for regulating these devices and there would be huge enthusiasm to try to convince the FDA that they didn't need to do this at all. But in fact, that's certainly not what I'm hearing.

And in fact, in a couple of the sessions and I think someone said that there doesn't seem to be much question in the belief that this regulatory approach has certainly improved quality, overall quality and therefore, safety to patients. It's a little hard to tease out of that exactly how much the software systems have contributed versus all of the other quality-related activities.

But it seems to me that the -- that a lot of the focus of what you're talking about has to do with the ability to have enhancements, the ability to move fairly quickly to integrate leading technologies and things along the lines of how does it work rather than is this trip necessary.

And then, of course, there is the difficulty of harmonization that it is, even globally, a small market.

And if you fragment that market into the United States and outside the United States, it's even smaller. And so this is not a good incentive for companies, even companies already in the market to be able to have an attractive business model.

So maybe, Jay, I'll ask you again. If you want these slides, Jay, I can give them to you soon after I write it all down. There seems to be a lot of interest in the possibility of harmonization. But yet, in most other aspects of regulatory affairs, we don't have global harmonization.

And so you know, are we -- are you whistling in the wind here? Or -- I mean, there are many other examples that we can illustrate of different regulatory decisions or even different approaches in the U.S. versus outside the U.S. And do you want to say anything more about that, Jay? Because this seems to be also one of the things that I keep hearing a lot about.

MR. EPSTEIN: Well, I think there's a shared goal of harmonizing because it could facilitate markets. And it makes it much easier for the whole business model. Many of the industries that we deal with are global. It

is a barrier to markets to have different regulatory systems in different countries. And we hear all the time from large manufacturers that they would like a simpler world, where it's common set of formats, common set of standards, common clinical trials, common requirements.

But then there are the realities. The realities are, you know, sovereignty, different laws, different practices and precedents. And so the reality is that it's very hard to get there, even if you have a shared goal between countries. So what are the baby steps?

Well, the baby steps are that there have been a lot of initiatives on information sharing. The FDA has information sharing agreements with easily a dozen and maybe more other regulatory bodies around the world. And we're capable of having a dialogue over pre-decisional matters. There are, generally speaking, constraints. In other words, we might be able to share certain protected information but not trade secret information. That might require the permission of the manufacturer.

But those dialogues are helpful because it enables the regulators to benchmark. And it sometimes -- I would say it often, when utilized, enhances our

database. In other words, we get information from other sources we might not otherwise get. But in terms of harmonizing the regulations per se, I don't think that challenge has been surmounted.

You know, the international committee on harmonization, which basically was driven by the large pharmaceuticals has made a lot of progress in establishing common guidance and common formats for applications. And FDA uses a lot of these now-globalized formats. That's a simplification that industry has appreciated very much. And it does save money and it does save time.

But -- and then there also have been some success stories with sharing of information, for example, on inspections so that we might recognize or receive the data from, say, an EU inspection. But it doesn't quite get to the point of reciprocal recognition of approvals. And that gets to the sovereignty issue. And it gets to the underlying laws being different. Because after all, each regulatory authority is following the laws of, you know, the country or the EU in the case where they have directives.

And so the conclusions have to be based on the

determining factors established in the law. And those are not the same. I can tell you right now that a CE mark and a device approval just aren't the same thing. So what does it mean to harmonize them?

Well, really, you can't harmonize them. You either have to agree on some new set of common standards or you've got one or the other. You know, you could decide to do things this way versus that way. But they aren't the same thing.

Now, are there initiatives in the device area? Well, yes. There is the Global Harmonization Task Force, GHTF, which is a body more or less like the ICH, which is looking at devices, looking at the framework for categorizing devices, looking at the standards for assessing devices, and seeking, ultimately, harmonization in this domain.

But I think that we're a long way from having harmonized regulatory systems globally. That's the bottom line. It's not lack of interest and it's not lack of appreciation for the fact that it could lower the costs of doing business and therefore, speed up, you know, progress. That's perceived and it's a shared view. But

actually harmonizing regulatory frameworks is just not imminent.

MR. McCULLOUGH: Great, thank you. Are there things about the discussion or the comments that I made earlier that anyone would like to disagree with or elaborate on? Celso, you disagreed with some of what I said. Yes, Angus.

MR. DOUGLAS: Can I just make a point, not a disagreement. You raised the question of, I think, does it matter if we don't have any large software providers. I think that was your question. And I don't know if it matters or not, but it does have consequences.

It does mean that when the pharmaceutical industry tell us that they feel they can transfer risk on things like keeping up to date on technology, keeping the best staff available for their IT systems, having the necessary backup systems, all that sort of stuff. They can transfer the risk to the providers for that with absolute certainty. That certainty may not be quite as great without -- that was just the comment I wanted to make.

MR. McCULLOUGH: Thank you. A couple of the

other themes that seemed to me from the discussion today and the four reports are it seems that one of the challenges of this discussion and this meeting is that there are multiple constituents. There are probably more than what I've listed here, but blood centers, large vendors, small vendors, and there may be others.

And probably each constituency has some particular set of issues. And to try to find a way to have a dialogue that would address all of those, and it may never be possible to make everybody happy. But I think it's one of the challenges of Don and Jim at putting this day together and maybe deciding how to go forward from here is to try to find a way so that a variety of points of view and constituencies can be considered coming to some sort of an approach for moving ahead.

And the fourth bullet point on here, process could be improved. Trying to avoid, Jay, asking you to go back to the microphone. But clearly, there is a lot of discussion about how to help vendors and blood centers understand when they need to go back for additional approval -- 510 approvals, what the -- how to speed and simplify the process and that sort of thing.

And I'm really not involved with this enough to -- it's not for me to come up with any kind of solution so much as that I wonder if the communication back and forth between the vendors and blood establishments in the FDA has been as effective as it might be in trying to help understand these things.

Maybe others of you would have some comments about that. I can only ask the people that I happen to know if they want to say anything. They probably don't. But Tim Coburn (phonetic) and I go back a long way. Would you like to add anything to this or anything else that you've said?

TIM: (Off mike).

MR. McCULLOUGH: Don't say no.

(Laughter)

MR. McCULLOUGH: How can the -- how can the process be smoothed not necessarily for the original submission but for, you know, steps to continue to enhance it, steps to put in the right kind of modifications.

TIM: Well, it's clearly -- in our session, we heard a lot of talking about communication and understanding what is -- it appears to be one of the

biggest in our -- group is that this -- that the timeline to get innovations out, and validation is a big part of that timeline, and the 510(k) process is a significant part of that. And although eliminating a 510(k) would eliminate a big chunk of time, eliminating QSR or the regulations or the confidence that vendors have in the process is it wasn't well received.

So it's clear that -- from our discussion that we heard that a lot of people like that -- the comfort of knowing the regulations are there to protect them and that not having them instills a certain amount of fear about what then -- is the burden then shifted to them and increasing the amount of work that they have to do.

Those are the types of questions that needed -- need to be addressed and answered. And you know, just -- maybe ISO -- accepting ISO certification following QSR would be enough to -- and subject to vendor's inspection -- vendor inspection by the FDA might move us in that direction.

MR. McCULLOUGH: Thank you. Okay, Marybeth, you're next.

(Laughter)

MR. McCULLOUGH: I was struck by your comment that if you -- if the 510(k) process was somehow decreased, that this would probably greatly increase the workload and complexity of validation, so -- and therefore, costs and everything else. So do you want to -- could you say a couple more things about that? Because it does make sense that there is some trade-off there. See, it's a disadvantage to have you (off mike).

(Laughter)

MS. BASSET: Well, I don't know what else to really say about it. But the -- you know, the discussion really was around we do feel somewhat protected because there is the FDA that is reviewing our -- the documents before it even arrives into our hands. And there is a certain amount of regulations that have to be followed like the quality system regulations have to be followed by vendors.

Lots of things about design control in there. So from a quality and regulatory kind of professional, there is a level of confidence and some security that when we get that piece of software, that we aren't going to find all the bugs and the kinds of problems that we might

find if we didn't have that kind of upfront review happening by the regulating agencies.

And so if we had to do more validation because we didn't have that assurance, we're probably going to find maybe more anomalies, more bugs that have to then be fixed. And that could just all start to drive up our expenses in the organization. We probably right now, internal to a lot of organizations don't have that internal expertise around validations and the kinds of things that you maybe would have to extend yourself into if you didn't have somebody else kind of reviewing on the front end. Is that what you were looking for?

MR. McCULLOUGH: Thank you. Are there any comments? Surely, someone that I don't know must have a comment.

(Laughter)

MR. McCULLOUGH: Well, let me go back through them briefly, just kind of a repetition of what the different breakout sessions supported. But some of these that struck me is -- first is the question of do the regulation, the 510(k) regulations inhibit development. And if so, how? I don't have the answer to that. But we

continue to think and talk about that. There does seem to be -- and we've already talked about this now a few times. There does seem to be the general thought that this does slow the implementation of enhancements or new technology.

But -- and also, I'm hearing a pretty good consensus that this has improved the software. A lot of discussion about what can be done to make it easy to -- easier to interface these systems with the other sort of non-regulated parts of the software. And it would even go so far as to -- as whether it could be defined that there might be some aspects of the software that don't impact patient safety the way Jay has described and therefore, might be free of 510 regulation.

The second breakout session also emphasized that this does ensure improved quality, ensures a standardization of processes. And the regulatory framework does provide a stringency to the vendors.

And the third session again seems to emphasize that this regulatory framework has led to improvements. But the question is whether in today, in 2008, whether the regulations are still properly focused and whether the processes are ideal. And of course, I've been hearing a

number of times that they may not be.

And the question of whether the current system is an actual barrier to improvements or if there are ways that it can be somehow tweaked so that it can at least not be a barrier but even possibly assist improvements. We've already talked about the harmonization or the segmentation of the U.S. and the non-U.S. markets. And the point, the first bullet point is what Marybeth was just talking about.

So Don, I'm not sure I have anything more to say. But I guess my job was to try to prod people and be provocative. I hope I haven't antagonized anybody and I look forward to tomorrow's discussion.

(Applause)

MR. DODDRIDGE: Jeff, I think what you have done is you have stimulated us all. And as we go to the next room for maybe a little refreshments, we could probably have some further talks. I've been asked by Bob that you do have evaluation forms and that if you would please fill those out and leave them at the table. And Bob and the other members from ABC will be gathering them.

And I think, if nothing else, what we've

accomplished, we've got all the players in a room together today to kind of discuss the issues. I don't think -- what we've seen is that the process is broken.

But if there are ways of improving the process, certainly, there can be further discussion. And I hope tomorrow with the two topics that we have coming up, we could further define what needs to come out of this session. But Jim, I think it was a session and it was well worth it. And I think -- and everybody in this room appreciates the effort that ABC has in putting on this session.

We will be meeting for a reception in the Potomac Ballroom, which I believe is on this floor, Bob. And that will start at 5:00. So let's carry on the discussion and also be able to relax a little bit after a long day, especially those that have traveled from the West Coast which are probably still suffering a little bit of jet lag. So thank you and we'll see you again tomorrow at 8:00 o'clock. And at 8:30, the session will start.

(Whereupon, at 4:51 p.m., the PROCEEDINGS were adjourned.)

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AMERICA'S BLOOD CENTERS

BLOOD ESTABLISHMENT COMPUTER SOFTWARE CONFERENCE

Maryland Ballroom
Hilton Washington DC/Silver Spring, Maryland

Friday, July 11, 2008

LIST OF PARTICIPANTS:

JIM MacPHERSON
CEO, America's Blood Centers

VICKI MOORE
Haemonetic Software Solutions

DON DODDRIDGE
President & CEO, Florida Blood Services

SHERYL KOCHMAN
Chief, Devices Review Branch, OBRR/CBER/FDA

LEONARD WILSON
Chief, Regulatory Project Management
Division of Blood Applications, FDA

SHELLEY LOOBY
Director of Regulatory Affairs,
Quality assurance,
Cerner Corporation

RODEINA DAVIS
VP CIO, Information Services, Blood Center
of Wisconsin

MARSHA SENTER
Products Manager

LINDA WEIR
Expert CSO, FDA/CBER

T.W. WALKER
Executive Director of Regulatory affairs
And Quality Audits, Canadian Blood Services

ANGUS MACMILLAN DOUGLAS
Consultant, Alliance of Blood Operators

JOAN LORENG
National Expert investigator, Biologics, FDA/CBER

TAMARA POLING
Information Systems Committee, AABB

JEFFREY McCULLOUGH
MD

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P R O C E E D I N G S

MR. MacPHERSON: Are we on? I'd like to have you take your seats please. I'd like to get started. I know many of you have flights today and we'd like to keep on schedule. So I'll give you about a minute to find your seat and then we'll get started.

(Pause)

MR. MacPHERSON: Good morning. It looks like everybody is pretty much in here. So I'd like to go ahead and get started. We had a busy day yesterday. We had good participation. We had good panels with a lot of good questions coming out of that. And today we're going to have a more perspective approach.

It's time to ask are there changes needed to enhance the state of blood establishment IT and discuss some possible solutions. Our first speaker will do just that. Vicki Moore (phonetic) is with us from Haemonetic Software Solutions. She has -- I'm looking for Vicki, there she is, before I start introducing her.

Vicki has had over 20 years of experience in blood center and hospital blood bank laboratories and 18

years regulatory experience with BECS, including a dozen 510(k) clearances. She is going to share her experiences from the perspective of the first vendor to receive clearance for both traditional and special 510(k) applications. Please welcome Vicki Moore.

(Applause)

MS. MOORE: So, good morning. I'd like to start out by thanking the ABC, especially for having this meeting, Jim and Rodeina particularly, because I know they've really been the driving forces behind getting this group together and I think it's been a really worthwhile exercise.

My objectives today, first to give you some background on myself and my experience, and then talk about our experience with the BECS process and FDA -- the good, the bad, and the ugly, Linda -- the value of the 510(k) process for BECS, and finally should there be a paradigm change.

I think I should start out by saying who is Haemonetic Software Solutions, I'm sure some of you have never heard of that company before. It was formed last year. IDM was acquired by Haemonetics early last year, and

in August of last year, Haemonetics decided to merge IDM with a company called -- it used to be called 5D, and merged them together, and so that became Haemonetic Software Solutions.

As Don said, we were the first to do traditional 510(k) and we were the first to take advantage of the special 510(k). So why did we want to be first? It was really a strategic decision. Our strategy was there were medical device regs that nobody knew how to apply to blood bank software or any kind of software, but particularly blood bank software as standalone. And we thought it would be good to get in on that from the beginning and help the FDA define what all that stuff means.

We thought that we could help define a development standard, if you will, kind of set the bar. And we thought within all of that we'd be able to develop a good working relationship with the FDA. We felt at the time that we had -- the software development methodology was far above our competitors. The reason that we felt that was that we had already been inspected twice by FDA before 1994 both by Sam Clark (phonetic) in as early as 1988 and then again in 1991.

I'm not sure why we had this dubious honor but I suspect it had something to do with some of the guidance documents that folks were talking about yesterday. Sheryl's 1988 and '89 documents about computer systems and blood establishments.

I think even more likely though the reason is that we were the developer for Abbott's DMS System and the FDA was seeing that system in lots of blood center laboratories all over the country. So I think that peaked their interest to look at us.

For those of you who don't know a Samuel Clark, he was probably the first BECS expert at the FDA. When Sam came to visit us even in 1988, he said you are a device manufacturer whether FDA says you are or not officially. And he -- both times he was at our place he inspected us with that in mind. One of our 43 observations was that we didn't have an MDR, we didn't even know what an MDR was.

My point in telling you all this is that even before 1994 we had FDA recommended, if you will, software methodology, development methodology in place. Because of that, when -- in 1994 when the call for submissions and they announced that we were all medical device

manufacturers, we had to make hardly any changes at all in our technical process.

So that gives me the perspective of knowing that since our technical process didn't change -- hasn't changed since then, that we could be relatively sure that all the things, all the experiences that we've had, had been as a result of the 510(k) submission process itself and not changes that we've had in our technology.

So what changes were -- we needed -- what changes do we need to do for the first traditional submission? Again no technical development process changes. We did have to enhance a couple of documents or design a traceability document and we were actually missing three documents that we needed.

So we worked with Molly Ray and Nancy Jensen who were the reviewers at that time, and created -- essentially made up what the hazard analysis should look like for BECS. And this will be interesting later when I talk about that.

We had to put more detail in our testing summaries and we had to invent this summary report of software development methodology you may or may not be aware of. It's a short three or four page document. It

just gives an overview of our software development processes and it's written strictly for the FDA. So it's kind of in a nutshell where you can see what our processes are.

This is a very busy slide as you can see, but it is a history of our 510(k) experience at IDM. The first two lines are the traditional 510(k)s that were the first to be cleared by FDA. You can see they both took over a year, a little over a year -- thank you -- also right here -- both of them were traditional because that's all we knew about at the time. And then in 1998 when the special -- the new paradigm was announced and the special 510(k) and the abbreviated 510(k) became available to us, we got on that bandwagon right away.

If you could see, as advertised it was cleared within 30 days, and then we had a whole string of specials and one abbreviated, all of which were under either the 30-day or the abbreviated timeline. And everything was going on very cool until we get down here in March of 2005 and the June 2000 submissions. And both of these I thought would be 90-day clearances and it turned out that they weren't, they were much longer.

So I thought it would be interesting from our perspective today to look at those two submissions and see what exactly was it that delayed those. We were -- we obviously seemed like we knew what we were doing, I thought we knew what we were doing. And all of a sudden in 2005, we've kind of hit the wall. So again the 2005 abbreviated submission was submitted in March of 2005 and it was cleared in 126 days.

And knowing what our history had been, it seemed reasonable to ask some questions. First, what did change since the last two submissions? Why would these be -- take longer to clear? What were the issues? And then what was the cause of the issues and the delays?

Interestingly, there were no significant personnel changes on either side in this timeframe. The same people were working for me at IDM, same reviewers were at FDA, and they're just -- there wasn't any difference there.

As I said, we have made no significant changes in our development methodology since the Sam Clark era. So it wasn't because we had started doing something differently in our practice. And there had been no new or revised BECS

guidelines, specifically BECS guidelines, published in that timeframe.

Then what were the issues for -- every time we send in a submission there, there's a request to clarify some documents or change them, or I usually forget to send something that they need, and you just expect that there's going to be some minor things that need to be done, need to be changed. We expect it.

But I was very, I guess, surprised when we found out that 10 years after developing the hazard analysis format and the contents with FDA, it was no longer acceptable. And then anomaly list, you're going to hear me whining a lot about anomaly list today. We had never submitted a standalone anomaly list in all our previous 10 submissions. A list of major software defects had been part of our hazard analysis document.

And up until this time, that was considered acceptable for that requirement that said we had to have an anomaly list. And then there were technical disagreements. The technical staff at IDM became very frustrated with the reviewers because they believed that the FDA really didn't have the depth of knowledge that they needed to have to

understand the discussions that they wanted to have about some of these questions.

And finally, after creating the anomaly list we were told that we had too many anomalies, and that we had to do something about that because our predicate device that we had named had no anomalies, if you can believe that. So for the first time in our experience, FDA required us to correct -- fix some non safety critical bugs. Our experience, our practice had always been the revision that we sent to FDA has no major hazardous defects in it, nothing that's safety related.

But it quite often has nuisance bugs that we know would be a pain for the users and they would raise hell with us if we didn't fix them. So while that submission is at the FDA being reviewed, we typically do a bug-fix revision that hopefully gets done about the same time as the submission is cleared, and then as that second revision they gets released to customers that has all the bug fixes in it or most of them.

But FDA thought that we needed to fix those before clearance. So we actually did that and then submitted version 1.1 for the clearance. And then to top

it off, we did that bug fix revision and FDA suggested that perhaps we should rewrite our designs specs because that was why we had -- that might be why we had so many anomalies since, because our design specs weren't complete enough. So we did that too.

Reasons for issues and delays and what cause these issues and delays -- a common theme is that I think the reviewer preferences change. It has been 3 years since our previous special and 6 years since our previous abbreviated submission. So it was normal for the reviewers to change some of their expectations as they had more experience and saw more things and kind of developed in their own mind what some of this stuff should look like.

Some of that usually is minor document changes but we did have some major ones. As I said, the hazard analysis that we had developed with FDA was no longer acceptable. I guess the ironic thing is I totally agreed with the FDA about the changes that they thought we should make to the hazard analysis, but I didn't think in the middle of the submission was a good time to have that kind of activity going on, when it wasn't going to affect the product at all.

And then the anomaly list, the famous anomaly list. You could say, well, we've been getting along without -- getting away with -- not having anomaly list for 10 submissions. So we ought to just be thankful and quit whining. But in any case the rules should be consistently applied and if the anomaly list was okay for those previous 10 submissions, it should have been okay with this one or there should've been some provision made.

We also feel that there is somewhat of a knowledge gap. It's not surprising that the reviewers are not technical experts, how could they be? The technology changes quickly and it's hard to keep up. And besides, we don't ask our software engineers to be regulatory experts. So why should we ask them to be technical experts, if you will?

And although we did win most of the technical disagreements that we had, they can result in a great deal of extra review time and discussion that's really aggravating when you're in the middle of -- when you're waiting for the submission to be cleared.

A submission is only as good as the documents that you send to FDA. One of the greatest challenges of

the submission process is to try to make documents understandable and anticipate the questions that reviewers might have and areas where they might be confused and try to head that off by the documents that you send them.

So we struggle with supporting the reviewers from a distant location knowing that it would be a whole lot better, whole lot easier, if were in the same room sitting across the table from each other so that we could actually be showing them these things, and it would expedite the whole process.

Then in May of 2005, as you heard yesterday, there was a new guidance document issued, and a joint document by CDRH and CBER, and it -- although it was released in May -- our submission was in March -- it really shouldn't have had any impact on our submission. But I can't help think that the reviewers were somewhat influenced by that. I'm sure they were involved in creating that document and now they had different ideas of what things ought to look like, like the anomaly list.

We do the same sort of analysis with the 2000 traditional submission that was submitted in June, cleared in 189 days. I think that's about 89 days longer than I

expected it to be.

Again, to go through the process of what changed since the last 510(k) which in this case was 2 years earlier, again, we had no significant personnel changes, no changes in our development methodology.

There was the new 2005 guidance document that we now had to work for. And we knew that one of the biggest areas in that new guideline was that we were going to have to start doing our traditional submission again because we were no longer going to be able to abbreviated for new products.

And then there is something I call "wireless hysteria" that was going on at the FDA.

The issues -- we had the usual changes and clarifications, mostly minor things, much the same as we had in the 2005 submission. Again, we had problems with our anomaly list. This new anomaly list that we had created, this new format in 2005, this time they said they thought it contain too many anomalies. It did have a lot of anomalies, but -- and they really couldn't -- they weren't written so that they could understand how serious they were.

So the only thing they could do is ask us to fix them, or we had to rewrite the anomaly list. Well, after many discussions with Linda, it finally dawned on me we were putting all these things on our anomaly list that they didn't want on there, that they wouldn't need to see. When they said, give us a list of your bugs, we gave them a list of everything -- enhancement request, things that would never be seen by the user. We just went crazy and showed them all of it.

So we renewed -- removed many of those defects, anomalies that weren't deemed pertinent to the user, and then we rewrote the remaining descriptions in less technical knowledge so that they could be understood. And that, I hope, is the end of the anomaly list story.

This product that we submitted in 2007 was very large and complicated. In fact, it was a change in intended use to that 2005 product. So, the documentation was somewhat confusing. We tried to present it in an organized fashion but it was difficult to review. In the end, we answered all the questions, and everything was resolved. But we did agree that perhaps we should do some more regression testing, which we did. And we found no

other problems with that regression testing.

This has to do with the 2005 submission guidance document again. As I said, we realized that we had to submit a traditional submission, so we had several discussions with the reviewers, several months prior to the submission itself to -- because that's been a long time since I had done a traditional submission.

So we had discussions about exactly what is it that they wanted to see in terms of testing documentation in particular. We exchanged, sent them documents to look at, they reviewed them, they suggested this is what we want. I was just absolutely sure we had that nailed. But they -- that I have really understood what they wanted, but at the -- in the end, that didn't turn out to be true.

And then the wireless and technology communication issues. These ran the gamut from our specifications list in the user's manual to code existence testing.

Reasons for the delays -- again, I think, the reviewers' preferences changed. It just has to -- it's part of the learning process that they see some document they like and then when one comes in the old way, I think,

they think, oh, it would be better if you did it that way, with no understanding of how frustrating that is on our side.

I'm an old blood banker. I have to be in control, and I'd like to know that when I send things in it's going to be accepted the same way as the previous one that's -- and that's just not always the case.

One of the examples -- to just give you an example, with this submission we had to reword the safety and effectiveness portion of our 510(k) summary which had been acceptable for all eleven previous submissions. Now, it wasn't a big thing, you know, it took five minutes to do what they asked. But it's just the idea of -- it's never right and you never actually feel like you have your arms around it.

The best example in this communication was with this testing documents that we had to send with the traditional. Again, I was confidant that I knew what they wanted, but when we sent it in, it turned out that they were significantly lacking. And then we had to send a lot more documents.

The good news was that we didn't have to do any

more testing. We just had to copy more documents and send them in. But it was still very frustrating because I thought I had foreseen and I had prevented this problem, and it turned out that I didn't, I'd wasted my time.

Clearly, the most frustrating issue we've ever had with the FDA is the wireless issue. Because of heightened awareness of the agency at that time about the potential safety issues associated with wireless, this turns into an unfortunate situation and there was unnecessary delays.

It was complicated and, I believe, worsened by involvement of CDRH. We essentially wasted 4 months creating some new documents and new arguments and additional artifacts that were specific just for the wireless functionality.

We weren't inventing technology here. We were following standard protocols that were used in the communication industry. And kind of the topper was, there was -- the wireless functionality that was in this product was exactly the same as the wireless functionality that had been in the 2005 product that received hardly any scrutiny at all. So it just didn't make sense.

But in the end we won out. Everything worked out, we did not have to change the product at all. Everything was good, but we were in a situation where, okay, we'd won the argument but our clearance was 3 months late, which is not acceptable.

I thought it would be interesting to look at a comparison of what I've identified as the reasons in both of these submissions and amazingly enough they're almost identical. There were different issues that caused those things but with the exception of the new guidance document that was issued in 2005, they are identical. And I could probably be convinced that we should put that -- the new -- the guidance document on the 2007 list too because it had to do a lot with the testing submitted.

I looked at time records and determined what was the most significant time-consuming post-submission work that we were required to do. Clearly, the rewrite of all the design specs, and the bug-fix revision in this abbreviated submission well accounted for the extra 36 days.

With the traditional submission, it was the anomaly list rewrite and reinterpreting all of those

defects, you know, a less technical knowledge. And then there's the wireless communication issue, just topped everything, clearly, accounting for more than 89 days.

So the summary of our total 510(k) experiences I've divided into negative experiences and positive experiences. And I'll do the negative first. I think there's a poor communication of requirements or inconsistent requirements. There is sometimes this IT knowledge gap that causes significant delays. And in the end, there's no obvious impact on safety or effectiveness after going through all of this.

There are positive experiences as well. There's no doubt that our user's manual and our development documentation is improved. It's better than it was before the FDA saw it. And the CBER reviewers are great, they're fair, they do the best they can, and we enjoy working with them.

I'm sorry if this comes off today like I'm being up on the reviewers, because that's not my intent. I'm trying to give you a sense of the frustration on the vendor's side and why it is we hate these things.

So what was the impact of the two submissions on

the product? Again, improvements to product-labeling and developing documents. The anomaly list, God love it, it's a whole lot better than it was when we started out. We have much better wireless communication specs and information in our user's manual -- our user's manual overall is better. We have more complete traceability documents and our hazard analysis has improved.

Having said that, there was no apparent impact on safety and effectiveness as a result of all of those changes. The hazard analysis looks better, it's more aesthetically pleasing, I guess, it makes more sense. But no new hazards have been identified as a result of that.

Testing -- we're not going to -- no additional testing required after all of that discussion and delay. And the wireless technology discussion -- again, no change to the product after 4 months of wrestling with that.

Knowing that I was going to be here today, I sat down with some of my product managers and QA people, and I said, if FDA says tomorrow we don't have to do -- we don't have to do 510 (k) submissions any more what would you change, what do you want to eliminate?

And I was surprised they wanted to eliminate that

development summary report that they only write for the FDA in the first place. But it's just a cut and paste every time so, it's not that big a deal to get rid of it. And they'd still want to write testing summaries, but they'd write them for a different audience. They'd be more technical and but they would still be there.

So if I look into my crystal ball, and say well, what would life look like without 510(k)s, what would be the impact on us and on you -- and in all of this I'm assuming that the BECS would remain classified as a medical device -- the only difference is, from today is that we'd no longer be a 510(k) submission.

If we look at it from the vendor or the device manufacturer's point of view, as I've said, I don't think there's any impact on safety and effectiveness in terms of the changes that we would make, we just wouldn't make many changes.

Clearly, we get the product to market quicker. We would eliminate the rewrite of a lot of the development documents which we do, making it less technical, so that they're easy to understand. We wouldn't do that any more. There'd be no change in our testing, either in the manual

testing or in the type of testing that we do.

And there'd be savings of many hours in the post-submission, pre-clearance work, probably some grey hairs and ulcers as well. If I look at it from the blood industries point of view, products and new functionality should be available more quickly.

Then probably, there'd be less clear labeling as the user's manuals wouldn't look as good, and some of the other documents wouldn't look as good. I think, there's no doubt that that is one of the benefits of having those people look at our documents. I think we're too close to it sometimes, so we don't really see the forest for the trees.

I think the most significant effect would be, at least in an initial perception, that products are less safe. That would, I think, cause people to do even more validation testing than they do now, which is a lot. And I think there might be an increase in litigation when the attorneys find out that FDA is not looking at these products anymore.

And then finally, if we look at what would life be like for the patients? Would it have an effect for the

patient? And I -- in my opinion, there would be none if BECS remains a medical device.

I feel like there remains a benefit and a need for FDA oversight. But is the 510(k) process the best method of ensuring that safety for BECS? I don't think so, and I think it's time to have a new paradigm. And it might look like this. BECS would remain classified as a medical device, there'd be no more 510(k)s, there would be quality system regulations that still followed all the general controls, and there would be improved field inspections. So, this is really an important one.

We need to have more BECS experts at FDA and in the field. It's a total waste of time when somebody else comes in and inspects us. It doesn't do anything for either side. It's very aggravating.

We -- as much a I dread it, when Sam Clark came the two times and Joan Loreng came a couple of times, we learned things from him and we had good reasonable discussions with him about what they saw. I think, when I look back on what we -- how we benefited from the Sam Clark visits and then visits by Joan, we did learn something and -- sorry, I lost my train of thought -- better inspectors,

yeah.

Oh I know -- that when we have these knowledgeable field inspectors come, it has a greater impact on safety and effectiveness I think of our products than any of the submissions that we made.

So with that I'll stop.

SPEAKER: Are there any questions of Vicky? Can you go to the mike please?

MS. KOCHMAN: Sheryl Kochman, FDA. I can honestly say that I can't argue with anything Vicky said. But there are some things, behind the scenes, that she's probably not aware of.

One of the issues with what is perceived as changes in reviewer preferences is that we have access to and we review MDR reports for software. We also have had some of our reviewers go out on inspections. And so, we see things at different firms that we feel others need to be cognizant of in their processes.

So while it may seem strange that we ask people to address nuisance bugs, some of those requests come from knowing that when there are nuisance bugs, the users tend to do things that override some of the things that were

good things with the software. Or they tend to want to find the quickest, easiest way to deal with that nuisance, rather than perhaps the correct way of dealing with that nuisance.

And so, yes, we have been probably asking for more clarification on things, for more explanation of things. Again, we do believe that a lot of what we're asking for is to enhance the user's manual and obviously you see some benefit to that.

But it's not that we're just making these things up. We're getting them from real life experiences. And I'd also like to mention the wireless hysteria.

(Laughter)

MS. KOCHMAN: It's not entirely hysteria.

MS. MOORE: Sure seemed like it.

MS. KOCHMAN: There have been cases and perhaps this is why you perceived the involvement of CDRH to make things even worse. CDRH gets reports of all kinds of problems related to wireless. And one of my favorites is that there was a laboratory that consistently had problems with one of their instruments, one that's -- they didn't realize it at first. They would periodically have problems

with this instrument, and no matter what they did on that day, they couldn't fix it.

So then they started tracking when is this happening. And they figured out it was always on a specific day of the week. Then they figured out it was always in a specific time range on that day of the week. And the more they trended when these problems happened, they were able to narrow it down to the truck that picked up the garbage.

The man who drove the truck, who picked up the garbage, would call in while the truck was dumping the garbage to let his route driver or his route manager know where he was, and what he was up to. And while he was there, his wireless signal was interfering with the instrument in the lab.

And so, hysteria? Yeah, maybe we overreact, but maybe we need some time to see how bad the problem really is. We know it's everywhere, and we hear a lot about interferences and so my comments.

MS. MOORE: Thank you Sheryl. I don't want to re-argue the wireless discussion. We won that, and I should just shut up.

(Laughter)

MS. MOORE: But our point of view from the beginning was we know wireless interferes with other wireless devices. And so our products were designed so that when that happens, they shut down, they did something that was safe and foolproof. The user would know, and that was built into it. But we couldn't seem to get that concept across to anyone, especially the guys at CDRH for a long time.

MS. KOCHMAN: I also wonder and I'm kind of feeling defensive about turnaround times. The time on the FDA clock for BECS reviews within the last several years has been 90 days or less, period, no exceptions.

And much of the time that people add on to that review time is the additional time that the manufacturer has to spend answering our questions. So clearly, if you make a submission for which we'll have very few questions, your review time on your clock will be shorter, and potentially, the review clock on our time will be shorter, because we'll find what we need right away, instead of having to dig through it.

And there are probably ways we can help deal with

that, but I do want to -- I'm proud of the reviewers, they are consistently getting things done by the 90th day. And that's not always an easy task to do.

MS. MOORE: I like the reviewers as I said. They're good people there, they're good to work with. Feel like they are under-resourced much of the time. But you know, I didn't mean to imply that they aren't doing the job. And you need to know that we want to send in the right stuff, if we just knew what that was.

You know, that's the frustrating thing, is I -- you know, I would have bet a lot of money, both of those submissions, that we had it nailed down, we knew what you wanted and then to find out that things were wrong, and that it's going to take weeks or months to get what you want, is just -- it just seems to be a -- there ought to be a better way to do it.

Thanks.

(Applause)

MR. WILSON: Just very briefly. I am Len Wilson. I was the branch chief for the first 5 years of the 510(k) program in the office of blood.

And I just wanted to make a comment about the

communications relative to technical terminology. As an example, when the 510(k) program first started, we were faced with 40 different manufacturers, all speaking of their version of IT to us. We were not naïve about IT, but everybody went to a different school just as in medicine. And some of the engineering aspects of discussions can get pretty complicated.

As an example, at one point I had to throw up my hands and say, we want to eliminate the word "validation" from any discussions because it means something different to everyone. And oh, by the way, if you are going to use a technical term, I need you to define it, and use it in a sentence, because it was just chaos trying to get simple communication.

Now I don't think this is FDA s fault, I don't think this is industry's fault, it's technical communication. And I would offer that one of the things that would be very, very valuable is to try to go with as much plain English as possible and try to avoid terms that have been known to have very ambiguous definitions.

Thank you.

SPEAKER: Thank you.

SPEAKER: Our next speaker today is Shelley Looby who is the director of regulatory affairs, quality assurance, at Cerner Corporation. And she is going to speak on the challenges of entering BECS software market. She'll compare the initial challenges of 510(k) submissions, how the process has evolved, and the future of the BECS' market place.

Please welcome Shelley.

MS. LOOBY: Good morning. I have to read the notes here but I do have everything right. I would just like to echo Vicky's thanks to the conference organizers; I know they did a lot of work. And as a vendor/ manufacturer, it's very pleasing to me to see all parties come to the table, the vendors, the users, the FDA. It's encouraging that we've had this meeting, that the discussion has been open, and I think it would prove to be very, very, useful going forward.

These are the objectives I'd like to cover today. I'm not going to read them. I'll go through them as we go through the slides. So in 1994, Dr. Zoon's letter dated 3/31/94 to the blood bank software vendors turned many worlds upside down. Many of us who are members of trade

associations, AdvaMed for example, knew what was coming. But to be honest with you, there's something about seeing that printed in black and white.

Overnight, for many of us, all our little IT shops became medical device manufacturers. We have a decision to be made, to remain in the market. And that we would -- we were going to be subjected to the device provisions of the Food, Drug and Cosmetic Act, and FDA's device regulations including establishment registration, product listing, pre-market notification, 510(k) approval, CGMPs and adverse event reporting.

So in the famous words of the group, Clash, "Should I stay or should I go now." For Cerner, it wasn't easy if not burdensome and an expensive decision. We had approximately 275 clients who were running our donor and our transfusion medicine software in production environments. Couldn't really just walk away at that point, in our opinions.

It also did not support Cerner's vision or mission to leave the marketplace, as our focus was on clinical automation, was solutions offered across the care continuum. So we weren't willing to walk away from the

blood banks to transfusion services, because of the 1994 letter. At least not right away.

In addition, we were actively marketing these solutions, both in the U.S. and outside of the U.S. So we had already established a prospective client base that we felt, it was not fair to have, you know, approached them, marketed and try to sell, and then have to withdraw that.

Lots of challenges, when that decision came forward. First was the initial 510(k) submission. As was discussed yesterday, what were we going to use as a predicate? And that we really didn't know. We had a lot of questions in this area. Formats, you know, what format would be acceptable to the reviewers. Can this be done without reformatting all of our technical documentation?

It was very pleasing for me to hear Linda talk about the fact that she likes to look at what we look at, and we have had conversations with Linda on the phone. I have an engineer in the room and we walk through that. And that's very helpful. We don't send them many FDA formatted documents. They get what our engineers use, what our validators use, what the regulatory affairs folks see and use. They get what we produce day in and day out.

And we really feel that that's the only way they're going to understand what it is we are doing. But initially we didn't know if they would really understand what our documentation was trying to tell them. So we struggled with the format issues.

We also struggled with the content. We were unsure as to what was going to be required for proof of substantial equivalence to obtain clearance. I have the printout which I know you can't see, but it's from (italics) Device Advice and it's a wonderful, at least in my opinion, information, group of various pieces of information about pre-market notification 510(k). Gives you an introduction what is substantial equivalence, who is required to submit a 510(k). Oh, if only I'd had this back in 1994, I would have been so smart and so confident that we were doing the right thing.

But I have it today and we use it frequently. It's a great teaching tool when I have new people come in that are going to be involved with submitting a 510(k), whether it be to CBER or CDRH.

The reviewers' guidance was also a huge boon. We understood a lot more than about format and content, but

back in 1994, we were struggling. We were making it up as we went and we were trying to figure out what the FDA wanted, they were trying to figure out what they wanted from us, and working back and forth. Giving the reviewers guidance put together was very, very, helpful.

So the challenge was initial 510(k), but at Cerner you're always forced to think -- 2 years down the road, 5 years down the road, 10 years down the road, we didn't believe that this was going to be a one-shot deal. We knew there were going to be future submissions. And as you can see, technically a new 510(k) is required every time a legally marketed device is changed or modified in a way that could significantly affect its safety and effectiveness.

How do we apply that to software changes? Software manufacturers as you well know make numerous changes to their devices every year, to address, both fixes and enhancements. So then what constitutes significant change in the eyes of the agency that would require us to submit new clearances?

Then the challenge was, if we keep submitting new clearances, are they going to be able to keep up. And so

it was a challenge on trying to think forward and figure out how we could make all of this work.

In addition, becoming a medical device manufacturer, we were going to have to comply with the current good manufacturing practice regulations.

Now, the QSRs. Non-compliance allowed agency to view the software as adulterated or misbranded, making its distribution illegal under the Food, Drug and Cosmetic Act. Obviously this is not where you want to go. If you've already got 275 points on production software, and you have other people waiting to get converted, didn't want to face enforcement actions which bring a whole another trail of tears, and can allow all these things to happen.

So it was a big change to Cerner, because it didn't just affect our blood bank team. They were going to have to follow the good manufacturing practices et cetera but it also affected our validation group, implementation team and support staff.

Because we don't make just blood bank transfusion and donor software, we make many other types of software, we have individual groups that will do design, development, then outside of say, that blood bank review, we may have a

group that does validation of a variety of different types of software, may do implementation of a variety of software and support of a variety of different types of software. So we had a huge education issue, because we were covering a large number of associates who are now considered medical device manufacturers.

Inspections -- that was going to be something new to us. We had had one previous inspection prior to 1994 and it was -- went very well, we had -- we did not have same people as Vicky did other than Dave Ferguson who was at our site several times and was a software expert and that was very helpful because he did understand our technical jargon and even though we had a cheat sheet that -- we tend to speak in mnemonics at Cerner, we had a cheat sheet for in the setup we say this mnemonic this is what we mean and we have given it to all of our investigators and it's very funny now, because they come in, they pull it out of their pocket and they immediately start speaking Cerner lingo.

But the fact that we were going to undergo routine manufacturer inspections was going to affect our day-to-day operations. And it was something we had to

consider going forward.

I went back and looked and we have a variety of associates involved with each and every inspection. It's obviously the engineering folks, the clinical validation folks, the technical validation folks, the implementation team and support staff, who, you know, take the calls and answer questions from the client as well as RAQA and executive management, so that there's a lot of people involved in inspection.

The average number of days, FDA is at Cerner for an inspection is 6.2 days. We have had eight inspections at our world headquarters location since 1997, and three at other Cerner locations and that's been since the inception of the quality system regulations.

The other thing that we were challenged with is that our blood bank clients were now going to be having additional scrutiny when the FDA came to their sites as they were going to be looking at their clinical software. And while we didn't probably anticipate this very well, we quickly came to he realization that when the FDA walked into a client's establishment, they were getting on the phone with us saying, okay, I need you to stand by because

I may have a question about this and about that, and, the FDA is here and I really want you to help me.

And of course we wanted to help them, and I have, to be honest with you I've had several conversations with field investigators who've been at client sites and they've introduced me over the telephone and we have answered questions and they have had, you know, mainly technical questions about the software, some of the -- some labeling questions, but we were just quite shocked when we got that first telephone call, and somebody said to me, "Shelley, the FDA's here." "Okay. Are you in the room with them?" "No." "Then why are you whispering?" "Oh, yeah, oh. Oh, yeah."

(Laughter)

MS. LOOBY: "I am calling because they're here and they have a question, I don't know if I can answer it. Will you be around?" And so it was just -- it was something that we had anticipated, and I can certainly sympathize with them because I know exactly how that feels, oh my God, what if they answer (sic) a question I can't answer.

And that was something else that we had to train

our associates form is that, you know, the FDA will be coming here and they will be asking you questions. Please, if you can't answer the question, tell him you don't know the answer, but you'll go find somebody who can answer the question. It's absolutely okay to say, "I don't know." And it was okay for the client to say, I don't know, but I am going to put you in touch with my vendor and they will answer the question for you.

We also realized that we had to do some client education around the fact that they were going to be working with an actively regulated device. And which is, you know, just another part of what we had to take on.

I think one of the biggest challenges we've had was not so much the 510(k) -- well we've had -- we had initial challenges understanding what it was they needed, what we wanted to send, and everything that was required. We have got an excellent support from the FDA and we too have had our bumps on the road with the wireless thing, and I think we've gotten that figured out as well. We've put a protocol together for all devices that Cerner does, for that.

But for us I think the biggest challenge not only

getting into the market but remaining in the market is the post-market surveillance activities. It's a requirement for all medical device manufacturers. We have a complaint filed, we have to file MDRs. It may have removals and corrections and recall. And this I think that we didn't really, truly appreciate. We always had had a complaint file and we've always kept it, long before I even got to Cerner.

But it changed quite a bit once we became an actively regulated device. Cerner has recorded, investigated, performed, corrective and preventative actions, for 162 complaints related to our blood bank software since 1994. We have a 12-page work instruction that supports our standard operating procedure, that supports our corporate policy on how you handle complaints.

And the complaint manager that works for me has been called lots of names. She's very particular about what goes into those records, has to have a lot of information in there, the chronology of the events, she's very, very particular. FDA reviews these every time they are in. We have never had any problems with it. I know that we have pushed back from associates right and left on

this, but it is something we are absolutely adamant about, have to be perfect.

And it takes 15 pages of word constructions to get what we need in those complaint files. Of the 162 complaints 6 of those met requirements for filing as a medical device report and 5 Cerner considered and handled as class II recalls.

So there's additional work from a complaint file if you bump up and then you have an MDR and there's more work involved. And then if you have a removal and correction or recall there's additional work. So you have to make sure that you want to make that commitment, going forward with this actively regulated device to handle all of the reporting.

I mentioned the client obligations. It was up to Cerner, in our opinion, to help educate the client base that they were going to have some obligations as well with this new responsibility as using actively regulated software.

We wanted to make sure they understood the new requirements and their effect on us because it was going to change how things were done. We were going to be slower,

we were going to require more documentation, more information from them when it came to, you know, a complaint. They had a responsibility to report themselves. They had to understand software system validation, the acceptance of increased cost of the device, and the support of the device, initial price of the device and support the device, acceptance of increased time to market, acceptance of fewer choices of manufacturers and devices. Because, while Cerner decided to stay in the market, as we heard yesterday there were several manufacturers who did not remain.

So I think overall, the challenges for us entering the market really come down to -- we had a huge lack of experience when 1994 hit. And we also had a -- while we had a lot of processes documented and everything was pretty much in place, the compliance, the strict compliance to it across the company because it wasn't just the blood bank team in our situation, it was probably one of the other big challenges.

The challenge to enter the market, as I said, for us was relatively easy, easy decision. The true challenges came in deciding to remain in the market. To be honest

with you it is -- it's a very small percentage of Cerner's business. It's an important part of the business. It was commitment to those folks that allowed us stay there.

But the challenges to remain in the market clearly are the resources. We feel you need experts in Cerner to make sure that the product is valid. So that means we have to hire blood bankers. And don't have a problem with that but you don't just go out and find a blood banker here anywhere that's, you know, willing to come into a medical device manufacturing house, an IT house.

Time -- this all takes a lot of time. And as you all know time is money. So it eventually comes down to money. Do we want to -- is it good return on our investment to remain in the market? Today, Cerner is in the market on our classic software for both transfusion and donor, those are clear devices. We have had clear devices on our Millennium platform although we are no longer remaining in the donor area with our Millennium software.

But it was a challenge that we decided to take. We're still there. And I can comfortably tell you that we're not making any future changes with regards to staying

in the market. And we are trying very hard to do what is right for the clients.

Cerner is also an ISO 9001:2000 and 1345 certified company. So that has, I think allowed us to use a lot of lessons learned with compliance with QSRs, to adhere to the standards for all of the company and it's not just our software, it's our service portion or ASP portion, everything is ISO certified.

Our challenge truly today is making sure that not only do we stay up with compliance with FDA regulations and compliance with ISO standards but we're dealing with the global situation as well. So we have regulations that we're dealing with in Canada, Europe, Australia -- you know the Mickey Mouse trail of M-i-c-k-e-you know, -- FDA, TGA, NHS, I mean the list is ever-growing, and the challenges to remain in the market for any software remain quite large and quite expensive.

Thank you very much for your time.

(Applause)

MR. DODDRIDGE: Are there any questions for Shelley?

She said wonderful since she answered all your

questions. So Bob, will you come and -- while Bob's coming up to load the computer here I'm going to introduce our next speaker.

We are happy to have with us today Mark Weischedel who is the senior vice-president and chief information officer of the American Red Cross. Mark will give us a basic understanding of the history, successes, and limitations of the Red Cross BECS system. He will also provide the Red Cross perspective on the barriers to adopting new technologies on integration with third party software under the current regulatory scheme.

Mark?

MR. WEISCHEDEL: Okay, thank you Don. And Bob, I'll keep things going while you do your magic here.

It's a real pleasure to be here today. And before I get started on the overview of the Red Cross and our experiences with BECS I'd like to thank the conference organizers, the speakers, and fellow participants from blood banking, the vendor community, and the FDA for a -- yes, -- I'd really thank everyone for a dialogue that I think is very valuable and long overdue. And for my part I've already gotten a lot of value out of the last day,

plus and I look forward to continuing that and I hope we do.

Right, so our objective is here to share our experiences and provide some perspectives on the current BECS regulatory scheme. I'll be speaking first on behalf of the American Red Cross and then later, most of my comments in terms of sort of, outlook, going forward, are relative to the industry as a whole.

So first, I -- there's no way to introduce the American Red Cross without, you know, sharing or reminding everyone that we are part of an international movement that's called the International Movement of the Red Cross and Red Crescent Societies. It's made up of three types of organizations, the International Committee of the Red Cross that is basically the owner, if you will, of the Geneva Conventions and provides our relief efforts in the areas of armed conflict; International Federation which is a loose federation of National Societies and there are about 181 National Societies of which the American Red Cross in one.

We are chartered by the U.S. Congress. We are not funded by the federal government in case any of you may be wondering about that common misconception. We have many

diverse lines of business, but the way that I tend to think about the American Red Cross as a whole, in particular from a technology perspective, is to think about the different operating paradigms.

You all know the blood business and know it well and you know that it's a business of constant demand, a high control imperative, a public health imperative, to provide a safe and adequate supply of blood. And we can never go a day without supplying blood. It's about as highly structured a business as I really can imagine.

Contrast that with our disaster business which we do both domestically and internationally. And the easiest way I try to describe it is that most of our chapters -- there are 740 of those -- most of those on most days don't handle any disasters at all. And those that they do handle typically tend to be single-family fires and those kind of things and that kind of scale.

After Katrina, we helped -- in a 6-week period, we helped nearly 2 million families with -- in response to that disaster. There aren't too many businesses I can think of that have that kind of variability and scale. So we have in scale -- also a word you'll hear me use a lot --

we have problems or challenges I should say, of scale, in many dimensions.

So our volumes you're probably familiar with, we collect about 6 million units of blood and about 770,000 platelet donations from almost 4 million volunteer donors. We operate through 35 blood services regions around the country, and we operate 5 national testing laboratories.

From an IT perspective, our customers are a combination of certainly, our employees and volunteers. We have, once again, many of those, about 35,000 employees, about 600,000 volunteers, although the volunteer field force changes. And as you might imagine, people sometimes volunteer on a regular basis, if they have the time to commit on an ongoing basis. And they may volunteer spontaneously in response to a disaster or something like that. So that's an ever-changing part of our workforce. And then, of course, we have the American public through our web presence, online training, and many other services.

Geographically, we're represented in every state of the country as well as U.S. territories. And we operate in military stations around the world, and once again we have 35 blood regions and 5 testing labs. The IT services

you can get a feel for what we do.

All right, so moving on to the BECS history. The -- our history, I guess, of the blood business started in 1940 with the pioneering work of Dr. Charles Drew. Now there are a lot of former Red Crossers here in the audience. Would it be inappropriate for me to ask for a show of hands, former Red Crossers? Mary Beth, would that be inappropriate?

MS. BASSETT: (Inaudible.)

MR. WEISCHEDEL: Yeah. Show of hands, former Red Crossers. Yeah, fair number. So some of you could probably -- could give a history lesson better than I can, but you have invited me here to do this so I'll share with you what I know. And ask you to be gentle with me if I get anything wrong and talk in terms of the early history.

But you know I'm sort of a new guy. I've been with Red Cross almost 5 years but it's still not unusual for me to run into people who can talk about, you know, the early, early, days of blood banking in the Red Cross. And I swear, some of those old blood bankers worked with Dr. Charles Drew himself. And I'm not sure of it, seems that way.

So really, I would describe the early days as a part of our grassroots heritage. The Red Cross started as a community service kind of an organization. There was at one time, upwards of 3,000 chapters across the country. Blood banking was done in those chapters as a community service. So while we operated under a single certain brand, at some points under a single license with the FDA, at some points, including now, under a single management structure.

But our heritage is a series of more or less independent blood banks and that technology followed with that. So prior to the early 1990s, essentially all IT was local. During the Elizabeth Dole era many of you remember, many of you were part of this, there was an effort called "transformation." And that resulted in among other things segregation of the blood business from the chapter and other businesses of the American Red Cross. And a component of transformation was a program called MACS which stood for Manufacturing and Computer Standardization.

At that time we operated somewhere around 50 blood regions and one of the, sort of, common threads since the early 1990s that continues to this day is a strong

trend toward consolidation and standardization. It's essential to our industry and I would say if there's one thing that I clearly support is you know through all of the day-to-day things and distractions and complexities that I think is important for our organization and that it's important for our industry, is standardization, so that we can interoperate, we can make changes more rapidly, we can assure a greater quality and at some point we can achieve some benefits of scale economies.

So that trend has continued to the point where we operate what was about 50 blood centers to, at the time that our National Biomedical Computer System, the outcome of MACS went live, we were down to about 40.

Now the -- I don't know all of the process that went through -- that the organization went through to select the software, but I do know the software that became our National Biomedical Computer System was purchased from a vendor, not licensed, but purchased.

That software was modified and adapted to the needs of the American Red Cross that are different, they just are. We have a National Deferral Donor database, we have -- we operate in regions that are expected to be

standardized, but that have some local autonomy. And that drives all sorts of different things that tend to be non-standard in our organization or at least that in those days they certainly were.

So the decision was made to essentially customize software. We can all look back and we can say, well, that was a good decision, that was a bad decision, but that was 15 years ago and we -- the reality is, in our case I'd say -- I'd call it a pretty unfortunate reality, the software that was chosen and modified in those days is still what runs our business today. And that's a real concern for us because it's pretty outdated technology.

So 1992, 1993, is when that decision was made and when development started, 1994 is when the FDA made a policy decision to govern, to regulate BECS as medical device.

So, as I understand the history, the team that was busy getting this program up and running, which by the way not only is part of transformation but also was a requirement of Y2K, so we had some hard deadlines in terms of when that needed to be done, so I suppose the team did what they needed to do to develop a 510(k) because that was

the new standard, submitted it; ultimately did obtain clearance.

But that was a new thing. And I know from my days of developing software that you develop things in a certain way and you document things in a certain way. Many of us who started technically, know that developers are not really all that fond of doing documentation.

So if you don't have standards, you know you may not have exactly what you want. And the organization had to adapt to that at that time. And some of that documentation once again is still documentation we have in place today because that's the software that we developed.

So there was a period of time after MACS was successfully, I suppose, completed, in 1999, in time for Y2K. There were a series of consolidations of blood regions which quite frankly had some problems. And we had some problems with merging donors and identifying duplicate donors and all of this sort of algorithms and so those kind of things that you need to ensure that you've got the right documentation and the right history for donors that prior to that were viewed as being different, we sort of hit a wall, quite frankly. We did some mergers and had some

problems, decided not to do that, going forward. So we sort of froze.

And there were some agreement with the agency that we weren't going to do anything unless we did it in a very, obviously, in a very safe and high-quality way. And we had some real constraints with the design of the software in terms of our abilities to do that.

So we're essentially frozen, if you will, on a 36 database structure that was developed, basically implemented in 1999 or early 2000 and so forth. And it's not really the structure that we operate our business with to this day. As standardization and consolidation marches forward, structure of our business has changed that -- everybody's business changes, but we are sort of stuck with that old structure.

So fast forward to a series of releases that were done, some of them done very well, the biggest of which was a release that collectively involved changes to about 15 different systems, in addition to the -- our National Biomedical Computer System. This release was so large that it was required for us to implement West Nile virus testing, that we sort of considered it kind of like the

mother of all software releases. We actually aptly named it the "Clara Barton Release." And the people who were involved in that take great pride in being able to accomplish that. And it's the last really major release that we've had in software several years ago.

We've implemented a collection software, we use health care ID, what we call our electronic blood donations record. We'd like very much to go paperless, we are not yet paperless. And one of the big successes that we had throughout the early years of the 2000 decade was getting through our Test Results Management System. And I'm going to cover a little bit more of that because I think it's particularly germane to some of the challenges around BECS.

Finally, if you look at the lower right-hand side of the slide you'll see a COT strategy. So you know after many years of trying to get NBCS to meet our needs and to adapt to the changing needs of the American Red Cross business it became pretty clear to us that we were dealing with technology that was outdated, and making incremental changes to that technology was a massive undertaking. It's in many cases easier to start over, probably more economical to start over, probably best for safety.

We also made some of these decisions around the business that we wanted to standardize with industry that we didn't want to be different from everybody else. And we think that's in the best interest of the industry in general. So we adopted a COT strategy. And as you all know when there aren't very many offerings on the marketplace a COT strategy is pretty difficult to execute. And that's the situation we've been living with ever since.

We did not have a 510(k) clearance software package that would meet either our functional requirements or our scale and performance requirements. And we're emerging I think -- the industry is in a much better place now than it was in 2001-2002 timeframe when we did the study. But we're still not there yet. And we've had a lot of challenges with performance and in particular the approach to having a single database across the national Red Cross system. And that which we are now revisiting in terms of having all over the safety features of a single database without actually having to have a physical database and we're working with our vendor partners to come up with the best design to approach that.

All right, so RTOMS test results management

system started with consolidation and standardization of our testing labs which again was a huge success story for the American Red Cross. We had, I learned at dinner last night with a colleague, that we had at one time somewhere around 50 blood testing labs that were consolidated down to I suppose it was about a dozen. And we're now down to five. They run common instruments, common assays and common procedures. And it's -- it is again a source of great pride and a source of great operational efficiency for the -- for the American Red Cross.

The technology side of that didn't come easy I'll tell you. We started with -- we had a package called DMS, some of you might be familiar with DMS, ran on HP1000. I never heard of an HP1000 until I joined the Red Cross. And we had a tough time keeping that thing up and running for a while.

So we had urgency at every conceivable level. We were out of testing slots and we knew that there was more testing that needed to be done. We had operational stability issues as well as having regulatory issues because the DMS was outdated software. We didn't know all the 510(k) ports, so there were limitations on what we

could do with that.

So we opted to -- we chose the IDM Surround software package through a series of many, many releases and project phases; ultimately did replace DMS in several other medical device packages with essentially a single central instance and multiple five national testing lab instances of Surround.

So now some of the challenges that we had do relate to BECS and they do relate to the regulation and our COT strategy, because essentially we have requirements that are unique. Certainly, we have requirements of scale. Now, "scale" is sort of an easy buzzword but you know what does it really mean?

Well, when you take our scale and you add the unique footprint that we have in terms of the relationship between our testing labs -- which again, bear in mind would be changing, so we started with 50, we went to 10, we're now at 5, who knows how many we'll have a few years from now -- right, so the relationship between a laboratory and a blood region -- and again bear in mind that our NBCS, our National Biomedical System that runs all of our manufacturing and collections and so forth, we have 36 of

those and now we have 5 testing labs. And we need the resiliency so that if, let's say we had a power failure in Detroit some months ago, and we need to be able to recover and do testing from one laboratory to the next, the relationship is complex.

So we introduced something into the software that didn't exist before, required -- I believe it did require 510(k) -- Susan or Vicky could clarify that, it's been a few years -- called the central repository. So we had our architectural landscape connecting our testing labs, our corporate data center, and our regions just as different from what anybody else in the industry needed and different from what anybody else did, and we needed to adapt the software to do that.

Now we don't want to customize software. In fact as a policy I'd say we don't really truly customize and modify COT software. We need the vendor to do that. And the vendor of course is not only servicing the Red Cross, they're servicing all of their other customers. When the Red Cross needs a vendor to do something we stress -- we call it "stress," -- on our vendor's resources. We recognize that. Nobody has unlimited resources.

And the -- this technology is complex, the business is complex and there's only so much of that expertise to go around. So these are some of the challenges that we've had with our TRMS system. But I'm very happy to say that that program is done and has gone very well.

So in terms of the strategic questions that we face, like any large IT enterprise we face a number of decisions and those decisions have what I like to call "long tails." You live with those for a long time. So in the early 1990s somebody made a decision what to do with our national, you know, collections, manufacturing, and distribution software that we call our National Biomedical Computer System. We're still living with that decision today. Decisions that had been made over the past several years are things that we'll live with for 5, 10 -- who knows how long, technology does change fast.

But the blood banks, in particular, because of the demands on control and quality don't change, don't adapt quite as fast as the field of technology does, so we face all of the "make or buy," whether to do enterprise or line-of-business systems. And given that we have five

different lines of business there is a tendency and under some regimes we've tried to standardize across disaster services and chapter environments and blood and those kind of things. And you can imagine with changing regimes and priorities and strategic programs how those kind of decisions might come and go over time.

You know we have to select whether (inaudible). I don't know that the BECS regulation is good or bad but I would say there's an influence. Clearly, how medical device software is bounded -- where the boundaries are and what the scope is of a medical device has relevance. It has relevance in terms of both, regulation as well as how you can integrate and what you can do with that software.

I asked -- during the breakout session I facilitated yesterday I asked of our software vendors how do you determine the boundaries of the medical device. Because, ultimately, that has a big implication for the footprint, it's going to occupy in our blood centers. And you know, quite honestly, I mean, as you might expect -- I mean, the vendors compete and so forth and there's no single right answer to that, but I think it's something that would be worthy of further exploration for our

industry to try to see if we can get, for one thing, some industry input in terms of where those boundaries are and make sure that it's meeting all of our requirements.

So the regulatory implications affect strategy in many, many ways. I don't believe there is a single right or wrong answer. I wouldn't advocate for a change or deregulation of software or something like that at this time, but I think change is certainly something that is needed for our business.

So the challenges of the regulation are well-known I think to all of us. We had many expert speakers over the past since yesterday that had dealt with these things. I'm not sure that I'll add much other than to what I have on the screen. What I will identify is a few things that I think are noteworthy that maybe haven't gotten a lot of attention in our discussion so far.

The technology trends toward agile methods, services-oriented architecture, software as a service, cloud computing, certainly, mobile and wireless technologies. These are things that may have implications in terms of how technology evolves in our industry, given that our industry is heavily guided and constrained by

regulation.

I don't want to say that regulation stops you from doing any of those things. I don't think it does. But I don't -- these things aren't all done in our industry today. We don't have, to my knowledge, any large-scale software as a service offerings for BECS as an example. We don't have large-scale BECS that's 510(k)-cleared that uses web services technology as an example. So it's hard to say how the regulations might affect that.

What I would say is that a partnership with industry will be, I think, very beneficial to allow us to find those answers and to position the way the regulations are evolved and apply to continuing technology change.

All right, so there have been many discussions. Obviously that's why we are here. And a dialogue has, I think, been enormously valuable to hear from the various viewpoints of many blood banks and vendors and the regulators. If we are to make significant change, and I do think change is a necessity, my take after about 5 years working with the Red Cross and now just a few months as a CIO, is that our industry is behind in technology, our industry tends to be for a whole variety of reasons slow to

adapt, and technology is at present, by my thinking, accelerating in terms of pace of change. After the client-server period of the '90s and after the early days of web, what we are now going into in Web 2.0 is a significant change in technology as well as changes in vendor consolidation and outsourcing and many other transit effectives.

So while the pace of technology quickens, and while we have -- that therefore presents significant opportunities for our industry, the question is, are we well-positioned to take advantage of those opportunities and advance the state of technology. And I would say, right now we have some work to do. I think we have a significant opportunity.

So what I would suggest is a three-way collaboration in some form, and it can take many forms, between the blood establishments working in concert between the technology vendors and the FDA toward some clear commitments. And I'll get to my ideas in a few moments, but I'd certainly like to hear everybody's ideas because this is about what's best for the industry.

So what I would advocate is a commitment, three-

way commitment to advancing the state of technology in the blood industry. Some examples of that are I would encourage modular and open architectures. I would develop, promote, and eventually enforce standards, for interoperability and data exchange. I would facilitate software development and entry, and yes, including the big players.

I believe there is role for the big players, not that necessarily they need to be the BECS vendors, but in our case, scale matters, and in many of your cases it does as well, and having a very, very reliable robust technology that exist in many, many layers of an architecture for any given solution.

The big players provide a lot of that technology and allow us to take advantage of what's happening in the rest of industry, so that we are not necessarily insular and limited by just what our BECS vendors alone can do. So I think that that should be a part of our equation going forward.

I'd like to see the pace of new technology adoption accelerated. My sense is we're getting better, but we have a long way to go. And as we can -- as we

proceed to try to take advantage of new software models like SOA and web services, and new deployment models like SAS and cloud computing, then we take advantage of many of the efficiencies and economies of technology development in the long term.

One of the things that strikes me, I've learned a lot in the past -- yesterday and today, around the various conceptions or misconceptions around the quality system regulation and 510(k). And I would welcome again in a partnership, shedding some light on this to what I would call demystifying the 510(k) in quality system regulation.

We've heard that there have been new entrants in the business that have sort of gotten it right in the first time. So it can't be that hard, right? At least, I believe that many organizations have now sort of mastered this, but to many blood establishments and some of the vendors, it continues to be a struggle.

And there are many different things that are misunderstood, and it to me takes on sometimes the air of a black art with very specialized expertise and interpretations, and I don't think it needs to be. So I think clarification there is important in many ways.

So that's a mouthful, that's a lot, and we've all had many ideas and you have to start somewhere. So what I would recommend as a place to start, and certainly again open to input because this is about what's best for the industry, is to start by establishing a forum.

Now, we have many. Somebody said something about the ABCs of, was it Shelley, the ABCs of our industry or something at the regulator. So how about these ABCs; ABC, AABB, ISBT, ABO, and I'm sure there are many others.

So well, I would suggest we pick one. And then let's find some interested contributors, and I'll raise my hand and say the American Red Cross is an interested contributor. And we look forward very much to working with the rest of industry again in a three-way partnership to progress the state of technology in our industry.

Some places to start, perhaps could be developing a manifesto in terms of what our statement of intent is to guide the direction of technology in our industry, and then some kind of working agenda. Set up some working groups for planning, education, and standards across our industry, and then set up some communities of practice, so we have the ability to socialize and share best practices across

the organizations and we can all learn from one another.

Our work with the FDA to prioritize, coordinate, and then develop some of the improvements, and again some of those are things that we've mentioned, some things that have come up with lots of good ideas. I don't claim all these are my own, but the things I like would be to -- certainly to facilitate BECS integration, and to recognize standards, so that if the industry works hard at defining standards, then we need the FDA to recognize those so that it can streamline adoption and approval from a regulatory perspective.

And certainly recognizing good industry practices, so we can sort of facilitate what is good from an agency perspective in terms of quality and safety. So those are the suggestions that I'd have in terms of our places to start. And again I'd like to thank you all for your time. And I'm happy to take any questions.

(Applause)

MR. DODDRIDGE: Do we have any questions for Mark?

SPEAKER: I think perhaps an opinion?

SPEAKER: I have no opinions. I like this

approach. One of the things I think that might be intelligent to do is make sure we include a broad spectrum of blood banks, because steps that might be good for like you and I, and may be New York might be using a sledge hammer to kill a fly for some of the smaller blood banks. So we have to consider adaptability, would be my only suggestion.

SPEAKER: And I had a feeling it was an opinion, but those are -- thank you, John. I certainly agree, yeah.

MR. DODDRIDGE: Any other questions? Thank you, Mark.

MR. WEISCHEDEL: Thank you.

MR. DODDRIDGE: All right, the last speaker of the day is Mary Beth Bassett, who is the vice president at Quality Management, Regulatory Affairs and Blood Systems. In her position, Mary Beth is responsible for the development and execution of all quality and regulatory programs, for UBS, and Blood System Laboratories, and the Blood Centers of the Pacific.

She will get BSI's large system perspective on BECS regulation, and present some questions for further investigation. Please welcome Merry Beth to the podium.

(Applause)

MS. BASSETT: You know, I never know whether it's a good or a bad place to be as the last presenter of the day. And put that on top of being a last presenter before a break. So I have a bit of a double whammy, I think, to overcome.

You know, it has been, as the other speakers have talked today, a really tremendous opportunity for us to get together from industry perspective, from FDA's perspective, and from our vendors to share ideas and our concerns. And I'm really very excited and looking forward to what might come out of this, what we might look forward to in the future.

So today what I'm going to do is talk to you a little bit about blood systems, experiences, and challenges with our computer systems. I'll talk to you about our automation, the history of blood systems, blood establishment computer systems, some of our current configuration, and the challenges that we have experienced, and then give us some ideas and food for thought looking into the future.

Most of you know a lot about Blood Systems, and

who we are, and how large we are, and where we operate, and how we're structured, and who our bosses are? So -- but I thought what I would do is give you a perspective about blood systems around our automation. We have 14 blood centers, and out of those 14 blood centers we have two blood establishment computer systems.

Our UBS centers use the MAK-PROGESA system and our California Centers use the Wyndgate SafeTrace system. We have two testing laboratories, and we use one BECS for that and that is Mediware and LifeTrak. On any given day at any given time, we have about 2,100 staffs that are using those systems. We have nine 510(k) approved or cleared devices in use or are on our horizon.

We have 16 standalone non-510(k) approved systems, and these systems are used to manage the information and data for about 1.5 million red cell collections annually. And of course the transaction of information from all of these systems, it occurs frequently and at a very high volume.

A little bit about our history. In 1983, is when we first implemented a computer system to automate our manufacturing process. And it was home-grown, we developed

it ourselves, and it was called PBOS. Then in 1994, as we've heard during this conference, this is when we had these devices of ours that were now going to be regulated through the 510(k) process.

In 1996 was the year that blood systems went under the consent decree. So that is the year that we made the decision that we're no longer going to be in the manufacturing or into the -- to making our own internal software. So we know that there are experts that do that. And we had a lot of other things that we need to focus our attention on.

So we spent the next three years and had lots going on, but we implemented three 510(k) cleared computer systems. In February of 1999, we implemented SafeTrace at our Blood Centers of the Pacific, all of our UBS centers in November of that year implemented PROGESA and then at the end of the year in December, our laboratories implemented LifeTrak.

This is just a picture that shows your blood systems today. As I mentioned our BECS systems are really kind of in the middle here, it the heart of our organization, and it manages donor eligibility through our

product distribution. We have lots of things that are hanging on here, whether they are through an interface or a data exchange, we've got our financial system Oracle that is interfaced, our LifeTrak system, which I mentioned is our lab management system.

It also has some 510(k) devices that are attached to it, that are feeding information into the LifeTrak system. We have a data warehouse that data is transferred, and then we have some things on the horizon, which is the transfusion service, component manufacturing, that's going to be automated through Atrius in the automated donor registration.

And then along the side are just some examples of some standalone systems that we have, and you can see many of those are what we use to support our quality system. So you can see we are really, highly automated, we use automation to manage our business in many different ways.

And because of this automation, most of you also probably have a very good change control process. But we worked many, many months to try to develop one that was very solid, very strong, and very rigorous to manage all of these automated computer changes and processes that are now

part of either the BECS system or our standalone systems.

We use this change control process for all of our software, whether it's a 510(k), whether it's a non-510(k), and we are really using this because we want to be able to manage all these projects successfully. We need to have knowledge of what's going on in the organization, and we need to be able to know which ones of these systems should be integrated.

We do all this with the oversight of a change control board, it's made up of our corporate office executives, and we really are the group that accesses the risk, establishes the resources, the money, the staffing, and approve the software to move forward.

So now moving away a little bit from really the who Blood Systems is and our computers, and focusing a little bit for you all on the challenges that we've had with our blood establishment computer systems.

I've captured them in these five areas, and we've talked a lot about these in the past day-and-a-half. But I'm looking at are challenges around growth and expansion, around our vendors, around our interfaces, around data warehousing in introducing risk.

So growth and expansion, because we have grown pretty significantly over the years, we have really demanded and had a quite appetite for more increase in automation. So that of course means we have a greater need to transfer this information.

The information needs to be interfaced, we need to be able to talk to all of these systems. Also our remote access has increased with Blood System's growth. Our testing laboratory has increased as well. The Blood Systems laboratories volume has more than tripled over the past 10 years.

And what that means is that the customers that we have and the clients that we serve have to have our data transferred into their computer systems, so that they further go on with their manufacturing. We've also got a great appetite now for data. We want to make our decisions based on data. We institute a culture of Six Sigma and process improvement in the organization and that comes with a high price tag of needing more data.

More data then means better reports, because you really need to be able to manage a business and make your decisions based on this data and these reporting

capabilities. And these have been real challenges for us. Also this growth and expansion in automation has really created the need for more technical expertise in the area of IT.

And this means technical expertise and quality, it means more technical expertise in our IT department, and these people are really very difficult to find. Another challenge that we've had is because of our growth, one, BECS is really not been able to meet our needs, and so we are faced with working with multiple vendors.

Now, before I get into this, let me just say that we have good working relationships, and good partnerships with most of our vendors. They really are trying to help us to meet our business needs with the growth of our organization. With that being said, we do understand and know that the vendor software is really not designed to support this intercommunication very cost effectively.

And most of this is due to proprietary concerns, you know, I get that as well. You know, I understand that its -- why does a vendor want to make somebody else successful and having us use somebody else's product, it's their competitor. All of that being said though, we still

have a real need for that information to be interchanged among all of our computer systems.

And product development time has also been a challenge. You know, we are an organization and probably an industry that we've got something we really want to institute the development time is taking a long time before we can get it into our hands.

Interfaces, is the third challenge for us. Now, certainly I touched on that a bit when I talked about the vendor kinds of challenges that we have. You know, ideally you would want all of your systems to be able to communicate with each other to have good interfaces. And as I mentioned, this is just not possible today because of the vendor's proprietary concerns and some of lack of cooperation with each other.

An example, I have a couple of examples here that I thought would be important for you to see. It's not just our 510(k) approved devices. It's also 510(k) being able to talk to our nine -- non-510(k) systems. We've had an initiative in our organization for some time now to automate the donor interview process.

And they are two separate BECS systems that we

need to have talked to each other, and we've had a difficult time getting an interface build. So we are using a technology on investigating the use of a technology called "Screen Scraping" to try to get the information from that automated donor interview into our BECS systems.

Now we know that that's not the best approach. We much rather have this interfaced. So -- but it is what we are left with today. And until we get that figured out, the screen scraping, we are going to be doing manual entry.

And I think it was Rodeina yesterday that talked about you got this great system, you get all this data in there, and then you print the record, and then you are now going to take and manually enter it into your BECS systems. Those are really not optimal solutions for a blood organization.

And we've had the same kind of thing as I mentioned with non-510(k). It was very difficult, very expensive to get our Oracle, our financial system to interface with our BECS systems.

The next challenge we've had is around reporting capabilities. It's really is some of our BECS systems do not have some of the best reporting capabilities, and I

already talked about our growing need and appetite for data and for better reports.

So we have instituted something called "data warehousing," and I'm sure lots of you are familiar with that. We are just talking information from our blood establishment computer systems and putting them in to a data warehouse, so that we can manipulate the data, look at the data, evaluate data, and create additional reports to help us to run our business.

These are non-manufacturing decisions. All manufacturing decisions are being made in our BECS system, but we want to make business decisions based on the information that is in our BECS, and we can't do it. And so we have to put it somewhere else in order to be able to use that information.

It also has some issues because we have multiple BECS. They have unique attribute, so it's not a one size fits all. So we have some complication in trying to get the BECS information into the data warehouse. And the other constraint we have is that it's not real time. We do not have the data transferred into that until -- till the end of the day.

We also have some validation challenges, you know, how much is enough, what should be validated, does it need to be validated, can we just validate the extract. So these are all some of the issues that we have around our data warehouse. And really the last area that I wanted to talk about and I've kind of talked about this in the other areas, but it's a really important one and that's why I have it up here as a separate challenge for us.

Now, whether it's the 510(k) submission process that's holding some of this BECS, whether it's the vendors not being willing to talk to each other so we don't get good interfaces, but whatever the reason is, we in the industry and in blood systems, are really having to put in solutions that we think are not optimal.

Screen scraping, filing, file transfers, extracts, doing manual entry are just some of them. And as we know, all of these methods is they are more error-prone and certainly they are more costly than automated solutions.

Okay, enough about all of that, about the challenges we have because I think if we look into the future, we can do some things that would help minimize and

may be make those kinds of challenges that we are experiencing, go away. So first of all, I think we should look at reducing the burden of the 510(k) process on the industry, on vendors, and FDA, and I think we've had lots of discussion as to what that might be.

More information, better guidance documents, may be more automation, may be we can automate the 510(k) process. So there is been lots of great ideas and discussions, and I think those things will be moving forward and that could help reduce the burden.

I think in the future, as we do today, we have to support the FDA to continue regulating our computer systems through clearly defined validation requirements, we talked about that yesterday, it's really difficult, validations is hard.

And clearly defined regulations, helping us to understand why we have the regulations we do. I really enjoyed hearing yesterday, because I think it's one of the things that we clearly didn't understand an industry it's -- which is the difference between a pharmaceutical and the blood industry, and why they regulated differently.

That was really very important because that is an

argument that we talk about or discuss because that an argument, but something that gets discussed, you know, in our organization, and now we've got some of that information. So I think more of that trying to get rid of some of the misconceptions that we have also will help us to be able to move forward, and then certainly through our inspections.

And as Mark mentioned, you know, to have us all be working on this together, I support that, I think we all need to be making the kinds of decisions together to figure out what we need to move into the future as far as, as the computer area. And may be most importantly is to get ourselves to think differently, while we can still be in compliance with the regulations and the requirements.

And I've two concepts that I wanted to bring to forefront here. I called them kind of out-of-the-box, but I think I've heard some people talk about this. So these aren't, so may be out-of-the-box, but this may be a couple of different twists. So I'm going to take the risk and show you some future thinking.

So one of the ideas might be to develop something you call a core computer system. It is a blood

establishment computer system that would be comprised of a 510(k) approved internal core. What that means is that we would want a streamline diversion of what is in our current BECS today.

You know, we -- our current BECS today is everything from donor eligibility all the way through distribution. So we would look at removing some of those manufacturing processes out of the large box. That small core would remain as the heart of the manufacturing system, and could this core be as simple as having labeling, quarantine, and inventory management.

Now, in order to do something like that, you would have to have an interface that would control this and an interface that would be approved through a 510(k) process that would allow us to hang the other parts of the manufacturing process into this core system. So core donor eligibility are testing, production and processing, be just an interface and not part of the core system.

Now, as I mentioned for something like that to happen you really would have to have a universal data interface standard. We just kind of made that term out. But it's just a standard way that we would have an

interface to share this information. Now, the core system would make the medical decisions, it would be interfaced with those modules, and those modules would be gathering and feeding that data into the core system.

So how might we move forward to think about whether this is even a possibility? We'd need to clearly define what part of the manufacturing process should be regulated through the 510(k) process, or are there some things, are there some activities that could just be regulated, that could just be part of validation, could just be part of inspection?

Can we -- meaning the vendors, FDA and industry, challenge our current thinking of what has to be in a medical device. These are kind of just big out there kinds of questions. Can we redefine? Are we comfortable to redefine where control needs to reside?

So just a little information about this interface standard again wanting it to be something that's approved by the FDA through the 510(k) process, could be applied for both 510(k), 510(k) devices, it could be between 510(k) and non-510(k), applications as well.

But you would want to make it part of the

submission, part of the approval process so vendors submitting for something, they would have to have this interface standard, this universal standard as part of their submission. And could it mean that if you have this approved 510(k) interface that there may be not some requirements for resubmission for additional devices that we've interfaced or when there's been approvals modifications made to the system.

Now, how we would do that? We'd have to really again work together with all of us to figure out how this could happen, but the vendors would have to build a design their devices to be compatible with this interface standard.

This is just a picture of what that might look like. In the middle, it's the core with labeling, quarantine and inventory management, with the other systems that are now interfaced with the standard. And then there are some quality systems that are listed there, and those could be interfaced as well, if you chose.

So could this help, could this help be the change that may be we are looking for to help us reduce some of the burden, that get us better communicating together

between vendors and FDA and the industry.

For blood establishments, it might simplify our validation, that'll be a good thing. It certainly would allow more flexibility and scalability, helps to reduce cost and our effort to associate it with these additional applications, and it would enable us to immediately adopt some of the state of the automation. So if somebody came out with something better in the area of collection or they came out with something better in the area of donor eligibility you could take what you're using lop it off, validate, put the next one on and go on about your business. But it would allow you to take advantage of new technology that becomes available.

For the vendor, the product becomes more adaptable to our -- to your customers. At the smaller course system may require fewer changes because again it's less complex. Your standalone modules may be easier to get 510(k) approval, not sure about that but again they are not as complex. They are just more of one area functionality, and those stand alone modules could be sold alone in our part of the great big system.

For FDA, you might see that this helps to

standardize computer systems and interfaces, decreases the complexity of the submissions again if there's more or less functionality to have to review and possibly could reduce number of submissions. So I just put that out there as some ideas and food for thought.

And in closing, I would just like to say that over the 14 years ago the Blood Establishment Computers became regulated as a medical device. And over the same past 14 years the industry has changed tremendously. It has grown and we are using automation today more than we have ever used automation.

So it is time for us and the industry and the vendors and the FDA to evaluate the application and how we are using BECS in the future. And this conference is indeed one way to do that. So I thank you, the organizers of the conference, and thank you all for your attention and that's all.

(Laughter)

MR. DODDRIDGE: Mary Beth, I think you stimulated some conversation; there is two up there already. Please state your name.

MS. NOZICK: Yeah, yeah. Hi, I'm Robin Nozick. And I'm from R F Nozick and Associates. But I think more importantly, because I've been listening to all of this and almost everyone has talked about interfacing, and so more importantly I am an executive committee member with the ISBT Working Party on Information Technology. And in ISBT we work as work -- in the working party as task forces. And since I don't want to duplicate efforts and since America is part of the world --

(Laughter)

MS. NOZICK: -- and we've been working really hard the Americans like Rodeina, Bonnie Lupo, me, on getting everyone to understand -- we understand we're part of the world. There is already a very active task force that has been -- was at first going to write standards for interfacing. And actually, our vendors are part of this, Be Close (phonetic) is part of this from Wyndgate. And there were people who come from Oliva (phonetic), the vendors to be part of the working party. So this is not a novel idea.

And what was discovered was there are standards already out there that are applicable to blood banking and

can be used. And I thank you, Mary Beth, because I think your idea is perfect, but I don't think we have to develop standards. That's what I'm afraid of is that we're going to go as Americans and develop standards. And we don't need to, the standards are there. And this taskforce needs more members.

We've already collected a list of device manufacturers who interface. We're looking for more names because Eva talked about this yesterday. I send Eva an e-mail this morning, and I can't turn around and see if she is there because then you can hear me, but Eva has received an e-mail from me that has Ms Pia Bruce' name. Pia is from Finland. She is the chairperson of the working party for information technology. She would love to have American participation.

So I'm throwing it out there that we're having an ABB meeting in October, we are having it in Montreal. I'm sure that if Pia knew there was this much interest by the Americans and the Canadians, she would make sure that she is there holding an interface taskforce meeting. I'll be glad to get everybody information about that.

But please don't go and make new standards

because the standards are there, and it's a waste of your time. What you need to be doing is working on this taskforce, and working with the rest of the world to write guidelines for how to use the standards. So that's what I --

MS. BETH: Excellent, I think that is great. There is no need to introduce and reinvent the wheel if there are things that are already available. I think it kind of goes to what we've talked about yesterday. There is just kind of a gap in what people know and the knowledge that's out there for all of us in the industry to even know that that's something that is going on. So thank you.

MS. NOZICK: I just have one more thing to add that that's one taskforce about a dozen taskforces and working parties that are already working in ISBT, and I don't see enough American participation. When I go to meetings I've seen a lot of your faces at the ISBT meetings. I haven't missed one in a couple of years. And we need more of you and there is -- we've donors, there is hemovigilance, and there is the validation taskforce --

(Laughter)

MS. NOZICK: -- that I co-chair. And Janet is

here from Wales. And we have guidelines and we'll be writing more guidelines a new version. And we'll be writing educational material. So please use those because you're my fellow colleagues and I hate to see people writing separate things when we have already worked really hard on it.

SPEAKER: My turn. Not enough, so I'm taking it down from the Puget Sound Blood Center.

MS. NOZICK: Okay.

SPEAKER: And I share some of your frustrations, working with vendors that will not interface with their competitors. It makes it much more difficult for the end users if we have to write our own interfaces. And I agree with Robin, there is already a standard. HL7 is used through out health care.

And there are standards for blood orders that are already defined. There are not standards though for interfaces between devices and there is really no reason why we couldn't add on to the HL7 segments to define those messages. No reason to reinvent the wheel and do it ourselves.

MS. BETH: Great. Thank you, both of you.

SPEAKER: Hello, my name is (inaudible). I'm working for Grifols. Grifols is a company that is a collector for plasma. So we have no blood but plasma, little bit different, but we are collecting 3 million units a year. So we are quite big. And I -- really, I'm happy to be here, and hearing that we are sharing all the same issues and the same problems.

And I totally agree with this approach of the core -- developing a core system for our industry and also regarding the interfacing problem. And I totally agree with Robin that there are existing standards, we do not need to develop these standards. So we can take a look at the existing ones. And also the big players are using it, I mean, SAP and Oracle are using. And you can have more information if you want in the Internet.

The standards are UDDI, so you can have a look at uddi.org to have the complete information about business standards and also WDSL. And I think that we can take an advantage of that. And that is not -- the question is not having the big players introduce it in our standard for the HL7. So it's just -- we can do the opposite, we can join this standard, and going forward, and take benefit of that

development, so.

And if you are developing this taskforce, for Grifols will be a pleasure to join, and to help on joining this efforts in this three ways so like joining vendors, FDA which is a very important thing, because its helping us a lot in developing more safety products and saving more lives. Thank you.

MS. BETH: Thank you.

(Applause)

MR. DODDRIDGE: We're opening some time for some panel discussions, so if you do have additional questions we're going to take a break. And I'd like to give you 15 minutes because many of you are checking out, and so let's try to be back here by -- between five and ten.

(Recess)

MR. DODDRIDGE: Okay, our final panelist is coming forward; if you'd please try to take your seat. Well, I think we've had a very successful conference, and I know that there's been a lot of questions raised, there's been a lot of proposed changes, there's been some status quo that we've come out of this meeting. But I think overall the best thing that's come out of this

meeting is that we've had everybody in one room discussing the issues.

And I think we're all here for the donor and the patient and I think we're to -- our job is to find the right decisions, to make the right decisions and take the points that have been raised and see if we can move forward. And I'm going to ask the panel starting with Rodeina to introduce themselves. Rodeina is the co-chair of the committee that helped put this conference together and has done a fantastic job, Rodeina.

MS. DAVIS: Thank you. Becky was my comrade in times, so thank you, Becky.

MR. DODDRIDGE: So you --

SPEAKER: You have a mike?

MS. DAVIS: No mike.

MR. DODDRIDGE: And give it -- if you want each of the panelists can give an opening statement and then we'll go to questions from the audience.

MS. DAVIS: All right. I think we started with the planning committee to put this program together, and the idea is as I said in my presentation to start having dialog. And from what we have witnessed in the last few

days, I think it's not only dialog, we had lots of great idea put on the table yesterday and today.

And I would either hope that as we move forward we will all partner together on this. I think more important to me what occurred today is we all were getting more and more aware of the role of system in IT in blood banking. And that is a message that we always wanted to get across to our organization, to our industry, and we're really trying to see how we best can meet our business strategy and provide patient safety as well as donor safety.

So I think together as a group we were able to accomplish a startup of how we can move forward with this, and I do want to recommend that we do look at what already exist. I think the FDA have quite a bit of documentation that I'm hoping that we can all try to find out more about them, and establish a mechanism how we can facilitate excess of these documentation, or maybe provide more training, or a better way of -- and there's then being and reducing all the misconception that we have two of the 510(k) and others.

But I want to mention there is as Robin said the

ISBT working -- IT working party that have done excellent job at trying to come up with some answer to some of the question that were raised today whether in the area of validation, the area of security, the area of interfaces.

And we have another taskforce working on the RFID standard, so we do want to figure out how the AABB IT committee that we have, the ABO IT committee, the ISBT IT committee, the FDA and all of us -- and the ABC IT committee. How can we all partner together and be come up with some solution that can really streamline our operation.

I do want to thank Jim and mostly D. D. Dodd for keeping with us, putting this program together because D. D. at the end, he is the one with the team, with the staff at the ABC, who need to work hard to make it happen with lots of support from the FDA staff. Thank you.

MR. DODDRIDGE: Thank you, we'll start with the far left, if you just introduce and if you have an opening statement short.

(Laughter)

SPEAKER: Hi, everyone, it's really short. I am the talking vendor. Rodeina asked me to sit up here, so

if you want to take pot shots at the vendors, please I'm the one. I think this really was a great meeting, and I really encourage you to keep continue with this meeting. The vendor community responds to industry needs, so please just keep going.

MR. WEISCHEDEL: Good morning once again everyone, I'm Mark Weischedel, American Red Cross. And I can't say enough about how important this session has been and in varying, sort of, small groups there've been discussions for many years as long as I've been in this business about IT and in index collaborating and working together towards in better solutions. So it's very gratifying to see this coming together. What I would say is that there are so many pockets.

I used to think Red Cross was the acronym sort of alphabets to and now I'm learning it's a blood banking industry thing. You know so the ABC, ABO, et cetera getting everyone together in this place, I think has been enormously beneficial to try to help get everyone onto the same page, and see if we can work toward a -- toward a shared agenda. And certainly the Red Cross will do everything we can to support that.

MR. DODDRIDGE: Okay, Jay.

MR. VALINSKY: Well, first I thank you Dr. Richard. I think that this has been a very successful meeting because there has been an open exchange of ideas and perspectives. I think what's probably important for me is to say what FDA hears. Obviously, we're not going to make policy from the podium. But I've heard that there is a general perception that bringing BECS under device regulation has added to the value of BECS that there isn't a strong desire for it not to be a device and comply with regulations.

The question is, how do we have oversight. I think that I've also heard that validation of software remains essential given the criticality of software in the blood system. I think what we've heard is that there is a need to make improvements that some of these improvements have to do with FDA process; it's been called streamlining of 510(k). I hear that, but I think there's also the issue of clarifying expectations.

I think that we've heard at least one very potent idea, which is a modular approach to regulation software that has to do with defining the boundaries of the

software, maybe that's what the core computer functions are that's a boundary over BECS as well as a standard interface.

I think we heard from Dr. Weischedel that we have to focus on a proactive collective approach to new technology that the essential frustration that's been heard here is that we're falling behind the curve being able to access and implement new technology opportunities, but that that would require a cooperative approach.

So that the regulatory requirements are understood, we have a clear idea of how to use these tools. So, you know, with demystification, cooperation, focusing on new technology opportunities, intra-operativity, reducing complexity of submissions perhaps reducing number of submissions.

I think those are the chief tasks that lie ahead, and I think that our main point here is that that we do -- we will cooperate in a collective effort, that I think it has to be approached in an orderly way.

Now, what are the critical oversight functions, who is best positioned to do them, is there some sharing of risks and burdens that could be changed between what FDA

does and what industry does and how to ensure accountability. You know, how much looking into the black box, how much really needs to be into the "white box." But I think that these are things that we can address together and that there is progress to be made here.

MR. DODDRIDGE: And last, but not least again Mary Beth.

MS. BASSETT: I think this would be an appropriate time for me to say dido. There isn't a lot more really that I can add, I'm really very encouraged though to hear from you Jay and the FDA that they're willing to kind of sit at the table and help us figure this all out, and so I think we just have to stay on it and make sure that we take these ideas and really turn them into actions. That's all.

MR. DODDRIDGE: Thank you. The format we're going to use, there's a couple of written questions that were turned in, which I'm going to bring up on the screen and Jay they seem mostly directed at FDA --

(Laughter)

MR. DODDRIDGE: -- so if you want to call for some help from senior troops you can and as we're doing that.

And when we finish those we will open the floor and please go to the mike and state your name, and direct it to -- if you want to direct to one of the panels or if you don't have one in particular they can take turns. The first one was --

(Laughter)

MR. DODDRIDGE: Would the FDA premarket approval process add value if the manufacturing firms were all certified to a regulatory standard? Who would like to take that? Jay, that --

MR. VALINSKY: I'll take it first crack at it. I think that recognizing suitable industry standards can only help. However, I think that it may not in and of itself be sufficient. There are firms that are ISO compliant and still have regulatory problems. So it's not a panacea, but I think it's an extremely helpful trend and that we can make use of recognizing more industry standards.

I think another domain that links to this little bit less specific to the question is this whole issue of the 510(k) being specially formatted for the FDA. This is something that we don't actually require, it sort of lives in the domain of misconceptions. We see providing an

example of what we want as simplifying things.

But if it's actually having up the perverse effect of creating more work, we can be a little bit more proactive saying well, we recognize documentation according to the following published standard.

And so it's along the general lines of industry standards, but certainly, you know, we're believers in ISO, we think ISO adds value, I think it's helpful I'm not sure we should just say its sufficient. In other words, if a firm is ISO compliant, does that mean we don't need to inspect. Well, I'd say, no.

MR. DODDRIDGE: This one has multiple parts, if the hospital system has corporate waste --

MS. BASSETT: Oh, Don.

MR. DODDRIDGE: Now we have -- okay.

MS. BASSETT: Can I just add to that, Shelley Looby, Cerner Corporation. I mentioned that we are an ISO certified company to two different standards, actually coming up on two more. I just want to say that while it helps I think greatly ensuring that we have quality processes in place, and that we have as a corporation, good practices worldwide for us.

Our audits from FDA as compared to our audits from our notified body are very, very different. And I do not believe that one could replace the other. There's very distinct things that the FDA is going to look at when they come in and there are very distinct things that BSI looks at when they come in. And while some of them do overlap there are very wide differences, and I personally don't feel that one can replace the other just from our experience.

MR. DODDRIDGE: Thank you. Our second question if the hospital system is corporate based and system upgrades or patches are requested by the manufacturer, how should the notification be made? Should it go -- I think what we figured out from this, should it go to the corporate first or should it go to the individual, hospital or user?

MR. VALINSKY: I'm not sure I can answer that because the answer might be either. Sheryl or Linda do you have an opinion on this. I mean, you know, one of you go to the mike though and --

(Laughter)

MR. VALINSKY: That works for me.

(Laughter)

MR. DODDRIDGE: And we've a couple of more questions.

SPEAKER: First of all, it may just be the wording is not right because we do not regulate hospital systems that is our sister agency CDRH, and I'm not sure they even regulate them. So was the question as to BECS?

MR. DODDRIDGE: I have no idea that is the way it's written, if somebody is in the room that would like to clarify that?

SPEAKER: Okay. Okay, if the BECS is corporate-based and upgraded, or patches, or requested by the manufacturer, how should the -- okay, to begin with I may be misunderstanding so correct me, but every bug fix, or patch does not need to be cleared through 510(k). It's only when it reaches a certain -- which I covered yesterday a certain level.

Once it reaches that level of affecting the safety or effectiveness in new intended use, you know, something wild and new technology then it should be made by the firm that manufactured it to the FDA, and I'm not sure if I still understand your question. But it should

be made as a 510(k), it could just be a special depending on what the changes were, but keep in mind every change does not require a new 510(k), certainly not bug fixes.

MR. DODDRIDGE: If you would like further clarification I think you can talk one-on-one after the conversation.

SPEAKER: Yeah, sure because I'm not sure that we understand. Okay.

MR. DODDRIDGE: Next one. Can the FDA investigate posting changes and 510(k) submissions?

MR. VALINSKY: Well, let me start on that. We have policies about when we post. Generally, the rule of thumb is if there are three specific manufacturer interactions that have a common thread that we can then post that. The dance here is between, what's a confidential communication with the agency and what's a policy update.

So we are mindful of the need for more than one user to get information when something has changed, and we are generally trying to use web posting more flexibly as opposed to issuing guidance document under GDP, which is a much more labor-intensive, time-intensive process for us.

So I guess the answer here is we appreciate the request, we are trying to do things of that nature, but we do have to figure out whether the issues are confidential.

MR. DODDRIDGE: Going under the next one. If their one submission -- is there one submission template for 510(k)s, there are many confusing documents that seem to require slightly different documents or information?

MR. VALINSKY: Well, I think the answer is that the regulations specify the categories of information in the 510(k) that's the fundamental framework. Beyond that we don't currently have more specific templates. In other areas, of regulatory submission, we have been moving toward what we call a "Turbo" submission, which basically is an automated submission where the template exists in a computerized format which, you know, you download and can fill it.

Now, we don't have this right now for BECS, but it's not inconceivable that we could try to move in that direction, you know, through some cooperative effort. So I guess the answer is only going to be partially satisfying to you that again the domain of information requested by the FDA is highly specified in the regs regarding 510(k),

but the details have to be called out of guidance now, and could be automated. And yeah, we'll think about that.

And special thanks to Allen because he's been a pioneer of this Turbo approach.

MR. DODDRIDGE: What is the difference between an Intended Use statement and an Indications of Use statement?

SPEAKER: (Off mike).

MR. DODDRIDGE: Okay, we'll then go ahead.

(Laughter)

MR. DODDRIDGE: Your turn.

SPEAKER: Whatever it is in the drug industry I know is very difficult with software, it was for me when they first -- I said, what -- basically it's the same thing for software. Sometimes the Indications for Use statements is a little bit longer in terms of what features you offer.

Often we get -- most often we get a 510(k) that actually has the same intended use and the same indications for use because all of our devices are used on the same population usually. So it's kind of a different concept, I can understand your frustration was trying to decide the difference between those two.

Jay, if you want to.

MR. VALINSKY: And well, Linda is behind you and he's quite expert in this, I was going to give a caveat to, go ahead.

SPEAKER: Well, to just to -- Linda gave a practical interpretation, there is nothing wrong with that. From a technical regulatory point of view the term "Intended Use" is unique to devices. It doesn't exist in drug or biologic regulation, indications for use.

Intended use is what the manufacturer of the device intends for it to be used, or how it is to be used, and it's a formal requirement that they needed to state that explicitly. They also need to add in an "Indications for Use" statement in other words a population number which is going to be used, how it is applied to et cetera, similar to how it is with drugs.

MR. VALINSKY: I think another way of looking at it, the Intended Use is generally broader and more general. You know, to determine the suitability of a donor would be a function of the software as a whole. The medical indication tends to be more setting-specific. So it says something little bit more specific about that

application.

So for example whole blood versus source plasma might be an intended use, I mean an intended use setting in medical indication, sorry, an indicated use. They are related though, and I think that's what leads to most of the confusion.

MR. DODDRIDGE: Well, Celso, we are ready to open the floor up, are you going to be the first one.

MR. BIANCO: Okay, it's a question for Jay.

(Laughter)

MR. BIANCO: But it's more of a request than a question. Jay, you mentioned on a couple of occasions that we have many misconceptions about the way the 510(k) work or the way FDA regulates what we do. Would you be willing to state a few of those so that we take home a message of what we have wrong in our minds?

MR. VALINSKY: Well, I can start and perhaps others who deal with this on a daily basis can amplify. I think the first misconception is you can't talk to us. We have really an open door policy, we engage in pre-filing meetings, you know, pre-510(k), pre-IND, pre-IDE, pre-BLA. We do this on a routine basis, it's a structured

conversation we expect you to come in, propose an agenda, you know, we offer a timeline for a meeting. But we do this routinely, and it's a tool that can enable better clarification in the FDA expectation.

What do you want to see on paper, you know, how to do want this indexed? If we put it in a CD is that enough, do we also have to send it to you, you know, on the web, things like that. So there is that opportunity. And along those lines this also the interactive review which is again has been part of CBER's practice for a very long time.

It's now in an agreement under the user fees for devices, but it provides once again a structured conversation, but one which is open-ended where a sort of small matter is going to be addressed informally. So I think the first misconception is that you can't just talk to the FDA. I think another misconception which is related is that you can't argue with the FDA.

(Laughter)

MR. VALINSKY: You know, we are science-based, and we tend to be convinced by data. And I think one of the things that has bothered me in the last day and a half

is that there is sort of paucity about data to help us understand the underlying causes of the current problems.

So for example we don't hear from the vendors who dropped out. You know, what did they think the barriers were, or from the vendors that opted out and what did they think that barriers were.

And then the flipside, is it better that those particular players, you know, did opt out or drop out because they didn't think they could comply with regulation. And the argument tends to be well, that's a bad thing that they are not playing, but maybe it's a good thing that they are not playing. But what's the evidence and I don't know the evidence. Jim knows the evidence.

(Laughter)

MR. MacPHERSON: Well, I don't have the answer to the question, but it prompted me to say that when we organize this we try to get two organizations involved Pharma and also to get its -- the health -- what it's called Rodeina, the health --

MS. DAVIS: HIMS.

MR. MacPHERSON: HIMS. And at first -- and Pharma refused to -- they said they wouldn't attend, they

didn't want to be involved, they didn't want to surface, they didn't want to be even thought to have the fact that they would be that their software would be regulated, and so they just -- they just ignored us frankly.

HIMS initially was very interested, and in fact they were going to provide a speaker on Microsoft -- for Microsoft to tell us why they don't -- they won't work with us directly and the person from Microsoft said, "Hell no."

(Laughter)

MR. MACPHERSON: So it's their absence here I think is probably tells you something, but do we have data, no. But I think their absence speaks volumes.

MR. VALINSKY: Well, it doesn't tell us all about their motives, only where they stand on it. I think that that hooks I mean I am getting a little bit away from the issue of what are misconceptions, but whether engagement of software giants is in and of itself a strategic goal here I think needs some clarification and I am not sure are we well-served or ill-served by the current landscape of vendors.

And the arguments been made that it's a more

robust system if there are more vendors. The arguments also have been made that the industry giants have more at stake to stand behind products, you know, they are not going to be able to walk away because that's the end of their credibility, you know, worldwide in many, many domains and not just BECS.

And on the other hand a small vendor might just decide well, this is not working for me whatever reason and you're on your own, you know, you can purchase rights to my source code, but you know you're on your own now. And the industry looks upon that prospect, you know, with horror.

So I think that there are unclarified issues with respect to the market forces, and that whereas the FDA regulation plays a big role in the landscape sort of the market forces, and I just think that there is a lot of reality testing that hasn't gone on to truly understand, you know, which force is dominant over which issue.

Okay, but just to come back to a few misconceptions, so I touched a little earlier on the misconception about the formatted document. FDA is actually a lot more flexible about the format of the

documents that we receive.

What we care about is that they address the correct issue, and that they should be interpretable. And obviously there are semantic issues and, you know, complexity issues and trackability issues and all of that, but fundamentally it's not a reluctance of the FDA to deal with alternative formats.

I guess another issue has to do with new technology. I think the point has correctly been made that when there is a whole new technology in front of the FDA, it's going to take us some time to work through the issues whether that's, you know, RFID and, you know, interference whether it's, you know, wireless which of course is related, whether it's open-ended use of web service. These things do present regulatory challenges.

But I think the misconception is that FDA is not willing and able to engage, we are willing and able to engage. It's just you have to approach us that way, say look, we have something new we want to put on the table here. I can tell you from the perspective of sort of, a broader portfolio within FDA.

We deal with a new widget or a new concept

everyday of the week. We are attentive to the need to define regulatory standards in the face of something new. That's not to say that it's done instantaneously, it's done deliberatively it means to be deliberative, otherwise we can make very, very big mistakes.

So -- but the misconception is why we can't engage FDA on that issue. And then I guess these are a little bit narrower, but it has to do with the whole issue of what to submit and when to submit. And I think that the rules tend to be a little bit more flexible than many vendors realize, you know, what, you know, bug fixes do you have to submit as a new 510(k). You know, how many things can you bundle and you don't have to file things like that.

But again I think the remedy to that partly it's guidance, partly it's conversation because it always comes down to specifics. If we had guidance, we'd still be in a quandary over the specifics. So I think those are the ones that leap out to me, there may be others that Sheryl or Linda or Joan might want to comment on, but I think those are core misconceptions.

SPEAKER: I think I commented on some of them.

MR. VALINSKY: The mike.

SPEAKER: -- I commented on the misconceptions I see yesterday and I don't know financial anyone has any other questions about that. I reiterate what Jay said about we don't care as -- we don't review for format, we review for content and other than repeat what I said yesterday I really don't have anything else to add.

MR. DODDRIDGE: Let's go to the next question, and if you'll come to the mike and state your name.

MR. COBURN: Hi, I'm Tim Coburn (phonetic). I'm a recovering vendor. And my question is to Nicholas. We heard -- brought up several times the issues of interfaces between systems. And as an expender I'm fully aware of that. And I want to get your comments. There are obviously technical issues that some of the ISBT groups are -- various committees, technical committees can address.

However, there is really the marketing issue and the proprietariness of trying to protect your customers. And I think if -- Jim, I think ABC and GSABC is kind of in a unique position to maybe force cooperation in their vendor or approval process to say if we can figure out the technical issues then if you want to be approved vendor

then here you got to play ball. I think that vendors want always to be treated the same. And so I'll cooperate as long as everybody else does. So I wonder if -- Nicholas if you could address that.

NICHOLAS: I agree with you. I -- as I mentioned in my opening comment. You, industry, the customers really can drive us a lot. And I heard multiple comments that some of the vendors don't work with you. It seems like there was a little bit of commonality there. And it is, as you said, if we all come to the table it's going to be a level playing field. If one of us don't we wonder why they don't come to the table. It is a little bit small market compared to the Microsofts and others. You know, I'm not sure if it's a niche market. In a way you could call it that. But it's hard with the small number of players to sit down and opening yourself up. Why isn't the others opening themselves? And I think ABC could help them.

MR. DODDRIDGE: Any other panel want to take this question, or have any answers?

SPEAKER: I would add that it is in the industry's best interest to -- for all of the vendors --

key vendors in this space to participate. And again the Red Cross will do what we can to support and encourage that. There is one of these things called the tragedy of the commons that if you don't have enough players, and if everybody's self interest in the marketplace doesn't reinforce certain behaviors, then the whole suffers. And we don't want to see that happen. And we've all had experiences that we want to learn from and apply on behalf of the whole industry. So without getting to specifics about negotiations with vendors and those kind of things I'd say that this is a key priority for us.

MR. DODDRIDGE: Any other questions from the audience? And I'm sure there are a lot out there. We got two coming forward. Jeff?

MR. WALKER: Tom Walker, Canadian Blood Services. Mr. Chairman, I don't really have a question. I actually would like to answer a question that Ms. Loreng raised yesterday, and also just provide a little bit of information supplementing my presentation that might prompt some comment from the panel, if I may.

First of all, yesterday Ms. Loreng expressed surprise that Health Canada had the power to inspect a

supplier that was not licensed when I mentioned that Health Canada had gone to visit MacVergesa (phonetic). In fact Health Canada doesn't have that power. They have the same powers as the FDA to inspect.

What happened with MacVergesa is that they were exercising an entity that they offer us, which is the on-site data review. We submit summaries of our testing and validation. When the reviewer goes over the summary if they find that their review would benefit from looking at raw data they give us a call and say, can we come onsite and look at the -- and go through the data and discuss it with you. They spend a day or two with us. They identify the documents that they need to take home for the file. And we find that this expedites the review from both sides, because it doesn't create a huge stack of paper. Well, we don't have to create a huge stack of paper that Health Canada then has to read through to find the appropriate parts.

Now, in the case of Mac I'm not sure whether Mac issued the invitation, because of the cost and effort required to copy all the paper and ship it across the Atlantic, or whether the Health Canada reviewer decided

that he would benefit from a trip to Paris more than the data would benefit from a trip to Ottawa. But at any rate it was not a case of Health Canada arriving and saying we're going to inspect, there was an invitation issued by Mac.

The second point, in my presentation I dealt only with submission of new systems. I didn't discuss how we handle upgrades and minor changes et cetera. Those are handled through the routine license amendment processes both for the Blood operators and for device manufacturers. Therefore, the submission requirements are scaled based on the risk of the change. Now, we still have long, meaningful discussions with Health Canada as to what the risk of the change actually is, and therefore how much data we have to provide.

But it does mean that issues like changing the system to export data to a financial application don't have to be considered. We had also -- in the process of those meaningful discussions about risk we've actually or effectively move towards the concept of a core system, or not requiring suppliers to modify their, or modularize their software.

And I saw we, I should give the credit to Health Canada, because they have looked at the manufacturing processes and stratified those according to risk so that we have the core manufacturing processes, and the software that supports those processes gets the full regulatory scrutiny. They have also identified low-risk processes, and software that supports that is regulated through inspection. So --

MR. DODDRIDGE: Thank you for those clarifications. Any follow up from the panel.

SPEAKER: That I would just have to say falls right in line with some of my thoughts and comments that I made about kind of a core system and what that would look like, and we'd have to really clearly define what that would mean. And then are there ways, as he just said, that the parts would be 510(k) cleared or for submission, and other things could just be reviewed on inspection or through validation. It does kind of fall right in line. And I really haven't gone to Canada. I didn't know what they were doing there. But it sounds very similar.

MR. DODDRIDGE: The Canadians come to Florida during the winter.

Jeff.

MR. McCULLOUGH: I have two questions. And the first one is for anyone on the panel and the vendors, I guess. In thinking of a totally different area, field that is beginning to struggle with how data -- electronic data is managed and communicated this deals with indwelling medical devices, pacemakers, cardiac defibrillators, drug infusion pumps and so on.

And in those situations the big guys are in the field, but those companies -- Medtronic, Boston Scientific, St. Jude and others -- are coming to -- we happen to live in the midst of most of them. And so they are coming to us saying that there are no standard ways in which that electronic output occurs. There is no way to ensure that it is compatibility, or talks to each other.

And as their patients who now have more than one implanted device sending off data systems they are looking for dialogue that would help to begin to figure out how to bring some cohesiveness to all that. And I wonder if that setting -- maybe it's a question for Jay, do you think that setting applies to the situation with Blood Establishment Computers?

MR. EPSTEIN: Well, I don't know the technical issues well enough to comment except to say that we talk all the time to our colleagues in CDRH to deal with those devices. For example in approaching the whole set of issues of RFID which have to do with, you know, using radio waves to transmit information, we've dealt with things of this nature. So I don't know what the prospects really are for standardized interfaces. But I guess I feel optimistic about it, that, you know, we've invented these technologies, we should be able to find ways to standardize their use. But beyond that I think it's more a technical question and a little bit out of my element.

MR. DODDRIDGE: Anybody else on the panel?

SPEAKER: Yeah. It's been mentioned multiple times, the HL7. It is a very good example how in the hospital market you really cannot enter without an HL7 interface in talking to the other systems. And I really would recommend to the industry to get involved. There is a special group already looking at defining the messages or amending the current HL7 standard to send to specific donator, or collection specific, manufacturing specific messages, and to be able to exchange data. I think you

just need to force us to do it. And you need to help us define what those standards are.

MS. DAVIS: And I was going to say almost the same thing. I think the vendor - we are waiting for our industry to tell them what we want, and as we put the taskforce together to look at system interfaces -- I mean, this has been going on now for over 8 years, and no activity (inaudible) has happened. We went after -- from both ways we went after it from the instrument to -- you know, all our instrument to the system, and then from a system to a system. And now that our instrumentation became really more network than have -- or have the capability of creating (inaudible) or interaction via (inaudible) transaction.

So we eliminated the instrument to system interface's need. And we said we need a standard to use in blood banking, in transfusion medicine that (inaudible) between talking system to a system. And that is the taskforce that I mentioned is going to have a meeting at the ABB. I think whoever is interested in this I will be very happy to send them the information. My e-mail is RodeinaDavis@ -- Rodeina.Davis@bcw.edu. And more activity,

I know that Wyndgate is onboard with us. We have some other vendor that are on there. But we do not have many blood banker on this.

MR. DODDRIDGE: Jeff, you had a follow up or --

MR. McCULLOUGH: I almost hate to bring this up, but it's a totally different subject. A number of times in the last day and a half it's been mentioned that whether or not you want to call this a niche market or a small market, the size of the market, and that determines of course the total revenue that's available to the vendors, and that's going to determine how imaginative you can be. I gather that there is some concern that some of the technology isn't as up to date as it might be, and enhancements don't come as quickly as they might.

And so to what -- I guess the question for you and other vendors in the room, to what extent is revenue and money really a major restraint in your ability to provide the kind of state of the art systems that we need.

SPEAKER: Yesterday. In Mark's group we kind of discussed this. And I realized yesterday when you say technology I'm not sure what comes to terminology. Is it functional requirements or using like RFID, and -- you

know, is the big question.

A lot of times the problem with technology is a lot of them come and go. If you look at the technology, especially in the past 10 years the number of new ideas that everybody jumped on, and then it turned out to be not working as advertised, we are a medical device as of to that. It is hard to implement and use a technology that's not really proven.

It's hard to be a pioneer and keep putting money when the customers are waiting for other functional requirements where we could, you know, expand our systems a little better. So it's hard to jump on the technology right away. RFID is working through a lot of issues that -- the technology is great, and it works great in other industries, but just because of the liquid it creates its own challenges, as an example.

MR. DODDRIDGE: Any other panelist want to comment?

SPEAKER: I would add that this is another area where terminology sometimes gets in the way. I mean, you know, many of the discussions that have occurred yesterday and today center around, you know, the state of technology,

and how do we as an industry avail ourselves of technologies and other trends such as service-oriented architectures and software as a service.

And sometimes we get tripped up in are we technology, and is it a question of technology readiness, or is it a question of do we have, you know, the economic wherewithal, do we have the right economic forces to encourage development in certain areas. And these are, I think to Jay's point, very complex matters. And the interplay of regulation and economic forces and technologies is not in many ways really very well understood within our industry. And so it's hard to say anything conclusive. But I think the question that Jeffrey asked is a good question around is there enough economic vitality, is there an adequate revenue base to drive and sustain technology advancement in our industry. And I'm not sure we have an answer to that. But I would be interested also in more information from vendors on that.

MR. DODDRIDGE: Okay. Jay.

MR. EPSTEIN: Well, I just wanted to add -- mention the fact that the user community is very heterogeneous, and, you know, you have very, very large

systems with highly specific needs. You have small operators with less validation capacity, and perhaps modest needs, and maybe they don't need the latest of the latest of the latest to address their structural problem.

So that's just another element that plays into this, that pace of change may be an advantage for example to a very large operator that needs a new technology solution, and it may be a disadvantage to a small operator that's doing, you know, very well, thank you very much.

MR. DODDRIDGE: Okay.

MR. ABRAMS: Hi, Philip Abrams from Talisman. I'm a vendor. Let me throw out a -- sort of a minority view. One of the frustrations that we often have is, you know, we have new technology. And what we see a lot in the blood industry is reluctance on the part of blood centers to adopt technologies quickly.

The cost of change is high. You've got, you know, regulatory issues, training issues, documentation issues, cost issues and so forth. And there are certainly times where we feel that, you know, we could move more quickly if only customers would adopt technology more quickly. I think some of the other vendors can certainly

share the frustration. For example, of how long it takes for customers to implement new releases. I mean, that's just the tip of the technology iceberg.

So, one of the things I'd like to see is figuring out ways that we can make it easier for the blood industry to adopt new technologies more quickly without a lot of the overhead that they currently have.

MR. DODDRIDGE: From a CEO's standpoint, better reimbursement.

(Laughter)

MR. DODDRIDGE: Any other responses to that?

SPEAKER: I think when we talk about technology, we are really not talking about, you know, using the widget that everyone else is using or the -- what we are really talking about when we have a technology, when we start talking about the capability to have open system, new system, to help us in creating some functionality, complex functionality, create intimacy with our donor, be able to do the donor questionnaire using the internet, make sure we have the proper security, make sure that we as organization, as an industry, have the ability to do it.

Now, given to implement that new technology that

you give us, as a vendor, and we are very happy that many of you are already offering some of these technology, we don't need to validate it in our environment and we need to make sure it's working. And the major problem we have right now is when we bring that new technology and we try to put it in, there is no way for us to integrate it with our BECS.

So if we're -- I mean, it's too silently -- it's, you bring the technology for us and we love it. I cannot use it because I'm not-- I don't have the capability to integrate it with my blood banking system. So the question is, as we said, that's why we are having this dialogue, for all of us to get together and say these are the right technology for us to use.

And we do study -- I mean, when we do study, for example, on the RFID, we're not saying we got to RFID tomorrow. We're doing a study. We are evaluating whether the technology is going to help us in streamlining or it's going to help us in patient safety. And we'll work together. We would like to put a group together to work together on this. But it is the idea of really getting together and determine -- I'd love to have your new

technology but there is no way for me to deploy it in my blood center because I have no way to put it into my system. So it's a catch-22 kind of thing.

MR. DODDRIDGE: Any other comments from the panel? Any other questions out there? I do think one point that was brought up earlier today I think from one of the speakers over here is the global aspect of what we're talking about. And I think that is very important. And we do have some success stories out there. Although we're slow and coming, we managed to implement ISBT code 128 with -- started out with ISBT and, I think, that was success stories on both sides of the water here.

SPEAKER: Hi, I am Dan Taksigi (phonetic) from Grifols in in Los Angeles. I work with Jazella (phonetic) from Spain, but I had -- I'm going to pick on Nick. But you recently had a 510(k) that got passed, and I was wondering if you could share some of the points, key points, that allowed you to get it -- put it through in such a short period of time.

NICK: We had this discussion again yesterday. So to some folks it's going to be a repeat. We believe that the 510(k) process and the regulation is actually a

good business. We have incorporated everything, all the documentation that we need to do into our software development process. So at the end of every release, we have the documentation ready and it's literally just putting it together and putting the other additional documents that we need to put on and we can easily submit.

And if you really look at it, other than the submission, you really should do that for any kind of product because it's just software development 101. You are going to start out with requirement, then you're going to create some specifications, you're going to code it and you're going to test it to make sure it works. We don't have really any problems doing any submissions. I mean, Linda, you are all reviewers, so please, you know, jump -- I mean --

MS. WEIR: What's the name of the software products --

NICK: Again, multiple times it's been brought up that you can't talk to the FDA -- we've been on the whole on a regular basis just to make sure if there were any issues or clarification needed to be, we just dealt with it, and it was a very easy process. Again, that's just our

point of view. Did I answer your question?

SPEAKER: Yeah, I thought you're going to say, a real software with zero bugs.

NICK: Yeah, right.

(Laughter)

MR. DODDRIDGE: Okay, any other questions? I can't believe after a day and a half of this stimulating conversation that we've had that there's no more questions out there. Are we all just burnt out? Last call for some questions or if the panelists would like to add anything before we close, and then we'll bring Jeff up to have some closing statements and follow up with Jim.

SPEAKER: Hello, I'm Jeannette Simms (phonetic) and I have come to see the conversation from Wales. I have had a fascinating couple of days here. I've heard such a lots. I'm sure most of you are aware we don't have to comply with the 510(k).

Personally, I think it's a great idea. I wish we had it. It would make my job a lot easier. Just a general observation. I understand why everyone is consumed about the speed in which you can implement new technology. I just wondered whether anyone has any information about

what's happening in Japan as they are the world leaders with gadgets and things. Does anyone have any comment on --

MR. DODDRIDGE: Does anybody have any experience with Japan on how they do it, any vendor in the room?

SPEAKER: Shelley Looby, Cerner Corporation. I do know that we have done significant amount of investigation with regards to Japanese device regulation compliance. Their rules are massive. And not only that, the import rules are very overwhelming as well. And we opted for not going into the market. We didn't have a lot of interest anyway from the Japanese market, and didn't feel that we could fund complying with their regulations and their import laws with the interests that had been expressed to-date.

Nicolas, you may have some other insight in that, but I do know that when we started investigating, and I used a person on my staff to start the investigation, we used a couple of attorney in Japan that do medical device law over there, I was overwhelmed. It was -- this looks like a cakewalk compared to what we had to deal with there.

MR. DODDRIDGE: Okay, well, thank you. I'd like

to go ahead and wrap this up. Jeff, if you'll come forward, and Jim, if you'll just follow Jeff. I want to take this last opportunity to thank you for attending this on behalf of ABC and our partners who put this together, and a special thanks to our committee who set up this conference and also to the ABC staff that did a fantastic job. Thank you.

(Applause)

MR. McCULLOUGH: I have no revelations. I'm really going to summarize or emphasize some of the things that all of you have discussed over the last day and a half. And I'll put these as short-term and long-term suggestions. First, I think it's apparent to everyone that this has been an extremely valuable day and a half, and again, I congratulate ABC and Jim and -- for taking the initiative to put this together. Obviously, it has benefits all the constituents.

And so I would assume and hope that this isn't the end, but actually it opens the door to establishing some kind of a forum that would include a variety of individuals such as IT vendors, IT experts from blood establishments, the FDA, but also quality assurance and

operations people. I think there are very few operations people here.

And so we'll touch on this a little bit more in a couple of minutes. And in fact, I think one of the vendors who I met in the bar last night, but I don't recall your name, has asked us to force you to do some things.

(Laughter)

MR. McCULLOUGH: And I think one of the ways that will happen is if we are sure that our operations people are also involved in helping to drive the process. Secondly, to mention the potential to explore interactions and collaborations with the ISBT taskforce on developing standards.

Thirdly, exploring ways to improve the interaction with the FDA, the jargon that's been used to streamline the 510 process. I think a number of people have given examples of how that could happen, and I don't need to refine them here, but also as part of this, to refine and improve the understanding between a vendor's blood stead and the FDA about validation expectations.

I think for others who didn't have the opportunity to be here in the last day and a half,

continued visibility from the FDA, and again, John's nice two or three slides illustrating to agency's vision of the difference between pharmaceutical and blood manufacturing, that really do form the basis for this approach that 510(k) regulations is helpful.

The other thing that has come out from a number of speakers, Mary Beth and others, is a my last bullet point on this slide, that if some attention can be given to defining those portions of software, which really have to do with blood safety and those portions which are more management functions, and then look at differences in applying the 510(k) regulations to those different segment software.

This is really not a series of longer term exactly recommendations, more like issues or things to consider. But several people have said, some more bluntly than others, that we are -- we, blood establishment folks, are actually part of the problem. We can't sit here for a day and a half and blame all this on the FDA regs. We have a role in all this, and so we need to look at ourselves and look for ways how we can help vendors to provide enhancements to improve the situation.

We have already heard specifically from Jay that the FDA is, as we know many of us, from other interactions with them, they are very willing to talk. They will look forward to talking and interacting and helping vendors understand how to work with them efficiently. But the blood establishments including our IT people, our QA people and our operations people need to take responsibility to help in this whole process.

Some of other issues, some discussion a number of times about large and small vendors, is this good, is it not good. The market will ultimately answer this for us. But it's mentioned in various ways that it is good, that it's bad, that we force out small vendors. And I think as Jay mentioned, and I think I did yesterday, maybe that's not so bad. If somebody doesn't have the expertise to go to the FDA, then maybe they shouldn't be doing this.

On the other hand, we also need to keep on open mind that there may be new people coming into this industry that would be able to make remarkable contributions. And so we need to be constantly aware of how not to prevent that.

A number of comments about the big guys aren't in

the field. And I mentioned yesterday and I think Jay did also, is this bad, is this good. The implication is that it's not so good, but if it is important, then what kind of strategies need to be put in place to entice the Microsofts of the world to begin to work with us.

And the next bullet point on here is, I'm not enough of a technology wizard to understand the jargon talk about that we don't have systems that are as contemporary as the technology would allow. Assuming this is true, what do we need to do, all of us, in order to help create an opportunity for those contemporary systems to be brought in to help us.

Jay made some nice comments yesterday about the difficulties in global harmonization. On the other hand there maybe some kinds of discussions that would at least be partial steps toward global harmonization that might make this field more attracting to some vendors, and those discussions would be important to initiate.

We've talked a little bit about the systems interfaces and also emphasize that maybe something that can be addressed as workgroups begin to be formed. Are there new technologies that should be implemented? If so, again,

those of us in the blood establishment particularly focus on operations have a responsibility to interact with the vendors to try to identify those opportunities and make it known to the vendors that we desire these kinds of enhancements to be developed and make it available to us.

One comment for the FDA. I started to put in parenthesis in the beginning of the second bullet point "Behind closed doors." I'm sure it's nothing that the agency could or would talk about outside of the privacy of their offices, but there must be some thoughts about a balance in which the regulations are appropriately applied, but also applied in a way that does make it possible for innovations to be implemented and moved ahead, particularly when these innovation might improve patient safety. And the fact is there is a balance between adhering to regulations but also applying those regulations in a way that allows us to continue to enhance our systems so we can do a better job and a safer job for making blood available to patients.

Another point here is what can we learn from the plasma industry. I'm delighted that Grifols is here, and there may be others that I don't know about, but they have

systems that obviously are very effective for them, and maybe there are things that we can learn from them.

Our last bullet point on here is -- here -- partly from some of the more recent comments, but also my own experiences in other aspects of transfusion medicine. And the fact is, I hate to say this, but those of us in transfusion and medicine and blood banking don't have a track record of being the most creative and imaginative and willing to move quickly to adopt improvements and enhancements. And I think that probably plays into the situation that -- in which we find ourselves.

That may be my last slide, but I must have passed over -- let me back up. I had one point on here that -- I guess I don't know where the slide is on here, but I had one line on here for Jay, that you -- in responding to one of the questions, you got a good start, and the line was that we should provide Jay Epstein the opportunity to give us his top 10 lists of misconception about the FDA.

(Laughter)

MR. McCULLOUGH: And you gave us two or three already. But I think that would be -- it is helpful. I think it's valuable for people, all of us here, to hear

your thoughts. And then by getting out those misconceptions, it's a way conversely to say here is how the agency is prepared and willing to work with everyone in order to move this field ahead. So thanks, I think, for inviting me to come.

(Laughter)

MR. McCULLOUGH: And that concludes my thought.

(Applause)

MR. MacPHERSON: Well, thank you. Thank you, Jeff, very much for doing this and for coming. Thank you, all for participating. I think you seem to be happier this morning than a lot of you were yesterday afternoon. Jeff said it kindly and I'll say it sort of bluntly, it was sort of amusing to me and very interesting to hear the friction going on back and forth between the QA and the -- quality people and the IT people because every time the IT people would say they wanted more choices, the quality people kept saying, "And things are fine just the way they are regulated."

(Laughter)

MR. MacPHERSON: So I think that it bespeaks that we have some job into actually even getting your own acts

together in terms of what it is that we want given the tension that exists sometimes between the quality people and the IT people and the operations people, and then the CEO, which there's only about three of four here, of blood centers who want to try to keep the cost down because of either competitive forces or because of the pressure coming from hospitals to keep costs down.

So I think that, as I said, we probably need to do a better job, meaning, ABC, in trying to figure out exactly what it is that our members want. This conference ultimately goes back to -- as a series of recommendations back to, both, ABC and ABO. As I mentioned in the beginning the mysterious alliance upon operators, this conference is under their auspices. And that it's not actually all that mysterious.

It's -- the IT effort is sort of fledgling at this point. It's headed up by Terry Harns (phonetic) from Canadian Blood Services and there is a member from each of the groups. Angus is part of the group from -- representing the European Blood Alliance. We are part of the group. As far as their next steps, I think we're going other try and feed into them what we heard here, but, of

course, there a more global component. The Australians are not here, for example, and there are very few Europeans here except for Angus and the young lady from Wales in terms of where that all feeds into.

But on a practical basis, I think we heard a lot of next steps. What we need is a lot more communication. ABC, with its members on these particular issues, I need to go back, we had started within ABC an IT working group. We started it primarily because of the launch of the data warehouse, but at this point it seems to need to take on a bigger role as to how it all feeds into the ABO group and who participates and how we better network within our own members.

As far as outside of ABC, if you add up ABC and Red Cross, it's 95 percent of blood supply, but that still leaves out hundreds of other players including people like Catharine Sasemu's (phonetic) group. And we can't -- we have tried to open up our membership, but our members won't -- don't seem to like that. But there are other avenues as we heard. There is a -- BB (phonetic) has an IT group, ISBT has a group, and a lot of the people that are in this room are part of those groups as well.

But I do think that as the communications gets out, it can only help. I will go back with Bob and with Rodeina, we will go back to the planning committee to see what they see in terms of next steps and to pick out from all the recommendations that came out in the -- especially in the last couple of hours of what we should pursue.

It's clear FDA is going back and taking a reexamination of what they do and how they do it. And as I think Jeff said, this is the beginning not the end. This is not a destination. This is the beginning of a process, and it's a huge process and it's an important process.

One thing I would throw out to the vendors, and it's just a thought, that -- and that is you don't have a umbrella group. You could have one. ABC and Red Cross together, especially under the ABO umbrella have been working more and more with AdvaMed. And AdvaMed has everything you need in terms of the relationships with FDA, the relationships on the Hill, in terms of any legislative agendas. They have the framework for dealing with proprietary issues and dealing with any trust issues for when you guys sit down and conspire to do whatever you need to do.

It's expensive, I know, to belong to AdvaMed, but at the same time, as I said, it is a group we are using more and more. They have a blood sector group, which tends to be mostly the other device manufacturers, if you will, the test manufacturers and the guys who make the blood bags and the freezers equipment.

Shelley is the only one here that I know who is part of AdvaMed concern, who is a member of AdvaMed. And how I first met Shelley was about 15 years ago when I was still in charge of the transition from Codabar to ISBT, you can see how successful I was in that, that we used to meet, I used to meet, with an IT group within AdvaMed that disappeared in the mid-1990s, I think, when the 510(k) regulations came out because, as Shelley said, some of the groups dropped out, and we haven't seen some of those vendors since.

But you new guys, the Wyndgates and the BBCSes and the Macs of the world are now a part of that group. So again, I -- that's a potential umbrella for you to work under, and I'm sure they would be happy to meet with you and at least talk about it and see what could be worked out. It would make it easier for us to organize you that

way. I know Tim Coburn said, you know, that ABC has the power to bring you together and ABB does and whatever, but I think it's much better when you do it within the framework of your own trade association.

So that was one -- so that just was one more suggestions. Let me see my notes here. I've pretty covered -- I did want to mention something. And we talked about harmonization, and my good friend Angus coined a term a couple of years ago that I think we probably should use more than harmonization and it is called convergence.

Harmonization is a difficult process because you're trying to fit things together that sometimes don't fit, and you're trying to impose regulatory schemes in some areas in which the culture is not ready for it or they do the same thing but they do it differently. But if everyone who thought about convergence in that we all want to be headed towards the same goal, that whatever we do, we can't ignore the fact that there is much more global market out there and that there are vendors that are becoming more global, some of them already are. And so we need to all be pushing in the same direction when we talk about this. Rodeina has -- is Rodeina in the room? Oh, Rodeina has

moved farther away from me. The --

(Laughter)

MR. MacPHERSON: One piece of advice for the ISBT group. We need to know what you're doing. I don't think anybody knows what you're doing, and that's the problem with having a trade association -- oh, no, it's not a trade association, but a professional society with one staff person, but -- and all volunteer are free. But again, think about using the existing routes whether it's ABC or ABB or whatever organization that does have the ability to get that information out to its membership and that -- so I would say, you know -- because we don't know what you're doing. I don't think most people in this room what you're doing, and -- or have seen your standards or read the efforts, which is a shame, which is a waste of time for you if people don't see it.

I think I have covered pretty much everything. As I said, it's sort of general. One thing, I think we have all your e-mail addresses, is that correct? Is that correct, don?

(No audible response)

MR. MacPHERSON: Yeah. We have all your e-mail

addresses, of those of you who registered and didn't sneak in without paying. And so what -- again, we need to talk about some specifics in terms of next steps, and I think what we'd like to do is within a couple of weeks just give you an update in terms of where we are and also let you -- at least give you a link to the transcript so you can enjoy this whole conference all over again. When you can't sleep at night, then you can read it over several weeks as you -- just before you go to bed, and so you'll know where everything is out.

Fill out the evaluations, please. We need to know what you thought of the conference in general. Even if you don't talk about specific speakers, we just need to know if you -- what we're hearing that people say this is worthwhile, whether it really was. Those are really important. Even if you just take two or three minutes to write a few comments, we'd like you to do that.

And I think I am done in terms of any comments and next steps. And I will just wish you all well. It's -- we're letting you out 45 minutes early. The gift of time is always really a great gift. Thank you very much.

(Applause)

(Whereupon, the PROCEEDINGS were adjourned.)

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